AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

MARCH 31, 2014

The Marriott Westshore
1001 North Westshore Boulevard
Tampa, FL 33607
(800) 627-7468

Committee Members:
Michele Weizer, PharmD, Boca Raton, Chair
Leo "Lee" Fallon, The Villages
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando

Board Staff:
Tammy Collins, Acting Executive Director
Jay Cumbie, Regulatory Specialist II

Board Counsel:
David Flynn, Assistant Attorney General

Participants in this public meeting should be aware that these proceedings are being recorded.

Monday, March 31, 2014 - 3:00p.m.

1. Rule 64B16-27.797
    a. Final language approved at February meeting
    b. Language noticed in the FAR on March 10, 2014
2. Immediate Use Compounding
    a. Type B Modified Class II Institutional Pharmacist 64B16-28.702
    b. Select Provision of 797 on Immediate Use
    c. Rule 64B16-28.100 (attached w/ recent changes)
    d. Rule 64B16-28.820 (attached w/ recent changes)
    e. Request for Declaratory Statement
3. Rule 64B16-27.700
    a. Impact of HB 3204 (November 27, 2013)
    b. Impact of Definition of Pending State Legislation
4. Compounding Inspection Forms
5. 2014-2015 Annual Regulatory Plan
    a. Required to be submitted by July 1, 2014
    b. Non-Resident Pharmacies
    c. Outsourcing Facilities
6. Compounding Pending Legislation
    a. SB 662 Non-resident Pharmacies
    b. HB 7077 Sterile Compounding

7. Compounding and Technicians
    a. Chapter 465.014, Florida Statutes (2013)
    b. Capter 465.003(13), Florida Statutes (2013)
    c. Rule 64B16-27.1001
    d. Rule 64B16-27.410
    e. Rule 64B16-27.420
8. Chair Report on FDA Inter-governmental meeting on Oversight of Compounding Pharmacies. (no materials).

NOTICE OF PROPOSED RULE

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

RULE TITLE: RULE NO.:
Standards of Practice for Compounding Sterile Preparations (CSPs). 64B16-27.797

PURPOSE AND EFFECT: The Board proposes the rule amendment for the specific purpose of setting the minimum standards for compounding sterile preparations, and for incorporating the following chapters of the United States Pharmacopeia: 797; 1160; 71; 85; 731; and 1231.

SUMMARY: The following chapters of the United States Pharmacopeia will be incorporated into the rule as the minimum standards to follow when compounding sterile products: 797; 1160; 71; 85; 731; and 1231.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST AND LEGISLATIVE RATIFICATION:

The agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the agency. The agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. Specifically, the Board considered that 21 U.S.C. §353a, as *amended* by Public Law Number 113-54 (Nov. 27, 2013), requires compounding to comply with the applicable chapters of the United States Pharmacopeia (USP) on compounding. Therefore, any economic impact is a direct result of federal mandates. Further, the Board considered that all institutional pharmacies are already mandated to comply with the compounding provisions that are being incorporated. Finally, the Board considered that since approximately 2008, Board rule requirements essentially required compliance with the provisions of the USP which are being incorporated. The Board considered that having to come into compliance with laws and rules that are already effective is not an economic impact that is applicable for consideration for this proposed rule amendment. No person or interested party submitted additional information regarding the economic impact at that time. Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.0155, 465.022 FS.

LAW IMPLEMENTED: 465.0155, 465.022 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Tammy Collins, Acting Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

(Substantial rewording of Rule 64B16-27.797 follows. See Florida Administrative Code for present text.)

64B16-27.797 The Standards of Practice for Compounding Sterile Products.

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order; and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office, or ambulatory infusion center).

(1) **Adoption of the United States Pharmacopeia:** Beginning on **October 1, 2014,** all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

(a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;
(b) Chapter 1160, Pharmaceutical Calculations in Prescription Compounding;
(c) Chapter 71, Sterility Tests;
(d) Chapter 85, Bacterial Endotoxins Test;
(e) Chapter 731, Loss on Drying; and
(f) Chapter 1231, Water for Pharmaceutical Purposes.

All referenced chapters of the USP, in subsection (1) are specifically referring to the United States Pharmacopeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the

effective chapter dates of December 1, 2013. A copy of the USP chapters referenced in this rule may be examined and inspected, but not copied, at the office of the Board of Pharmacy in Tallahassee, Florida. A subscription to all relevant chapters is available for purchase at www.uspnf.com.

(2) **Minimum Standards:** The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) **Current Good Manufacturing Practices**: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Federal Current Good Manufacturing Practices per 21 C.F.R. §§ 210.1 - 211.3.

(4) **Specific Exceptions to the United States Pharmacopeia**:

(a) Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.

(b) USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs)(i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 (see *Table* 1) environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month.

(5) **Additional Exceptions**: The Board encourages the use of a Petition for Rulemaking to inform the Board of a request to add an additional exception to subsection (5) of this rule. A Petition for Rulemaking is controlled by section 120.54(7), of the *Florida Statutes*.

(6) **Rule Conflicts**: On **October 1, 2014** this rule shall control notwithstanding any rule to the contrary located throughout the provision of Chapter 64B16, F.A.C. Upon the effective date of this rule, the board will begin the process of repealing all rules that conflict with this rule.

THIS RULE SHALL TAKE EFFECT OCTOBER 1, 2014.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History–New 6-18-08, Amended 1-7-10, _____.

The Board has determined that posting the material on the Internet would constitute a violation of the federal copyright law. At the time of adoption, the copyrighted material may be viewed at the Department of Health, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254. The incorporated material will be available for public inspection and examination at the Department of State, Division of Library and Information Services, Administrative Code and Register Unit, Room 101, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-0250.

NAME OF PERSON ORIGINATING PROPOSED RULE: Compounding Rules Committee
NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 11, 2014.
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: December 20, 2013.

64B16-28.702 Modified Class II Institutional Pharmacies.

(1) Modified Class II Institutional Pharmacies are those Institutional Pharmacies which provide specialized pharmacy services restricted in scope of practice and designed to provide certain health care pharmacy services that are not generally obtainable from other pharmacy permittees. These specialized institutional pharmacy practices are generally identifiable with short-term or primary care treatment modalities in entities such as primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions. Medicinal drugs may not be administered, except to patients of the institution for use on the premises of the institution, in any facility which has been issued a Modified Class II Institutional Pharmacy Permit. All medicinal drugs as defined by Section 465.003(7), F.S., which are stocked in these pharmacies are only to be administered on premises as defined by Section 465.003(1), F.S., to inpatients on an inpatient or in-program basis. In-program patients are defined as those patients who have met program admission criteria required by the institution.

(2) Modified Class II Institutional Pharmacies are categorized according to the type of specialized pharmaceutical delivery system utilized and the following criteria (Categories are designated as Type "A", Type "B" and Type "C"):

(a) The type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility,

(b) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist shall provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.

(c) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(d) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(3) All Modified Class II Institutional Pharmacies shall be under the control and supervision of a certified consultant pharmacist.

(4) The consultant pharmacist of record for the Modified Class II Institutional Pharmacy shall be responsible for establishing a written protocol and a policy and procedure manual for the implementation of a drug delivery system to be utilized and the requirements of this rule.

(5) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health.

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A" and Type "B" as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A" and Type "B" Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) The policy and procedure manual of facilities which are issued Type A Modified Class II Institutional Permits shall provide the following:

1. Definitive information as to drugs and strengths to be stored.
2. The establishment of a Pharmacy Services Committee which shall meet at least annually.
3. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
4. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
5. Provisions for the utilization of proof-of-use forms for all medicinal drugs within the facility.
6. A diagram of the facility and the security and storage of the medicinal drugs.
7. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide

the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.

2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

4. Provisions for the utilization of a perpetual inventory system for all controlled substances, injectables and other medicinal drugs as required by the Pharmacy Services Committee.

5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(c) The policy and procedure manual of facilities which are issued Type C Modified Class II Institutional Permit shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.

2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

4. Provisions for the utilization of a Medication Administration Record (MAR) for all medicinal drugs administered to patients of the facility.

5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(7) Controlled drugs as defined in Chapter 893, F.S., stocked as provided herein within a Type "A" Modified Class II Institutional Pharmacy shall be stocked in unit size not to exceed 100 dosage units unless an exception thereto is granted by the Board of Pharmacy. Proof of use record sheets showing patient's name, date of administration, initials of person administering drug, and other pertinent control requirements are required for both controlled and noncontrolled substance medicinal drugs in Type "A" Modified Class II Institutional Pharmacies.

(8) A Modified Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

Specific Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c) FS. History–New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01.

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at http://www.doh.state.fl.us/mqa/pharmacy or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595. Inquiries regarding the status of the application or license verification may be obtained at http://www.FLHealthsource.com. The application must be accompanied with a $250 initial permit fee, payable to the Board.

(1) –(7) NO CHANGE

(8) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, any pharmacy engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile Compounding Permit Application and Information," effective May 2013, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-03142.

(a) All applicants that hold an active pharmacy permit that are currently engaged in sterile compounding have 180 days from the effective date of this amendment (eff. 9/23/13) to obtain a Special Sterile Compounding Permit. All pharmacies, which obtain the permit within the 180 days, on or before March 21, 2014, are exempt from paying an additional application or license fee.

(b) Applicants for a Special Sterile Compounding Permit must:

1. Comply with all permitting requirements in subsection (1) of this rule;
2. Designate a prescription department manager or consultant pharmacist of record.

(c) The permittee and the newly designated prescription department manager of record or consultant pharmacist of record shall notify the board within 10 days of any change in the prescription department manager or consultant pharmacists of record on FORM DH-MQA PH10, "Prescription Department Manager Change," effective December 2010 or FORM DH-MQA 1184, "Change of Consultant Pharmacist of Record."

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13, Amended 9-23-13.

(8) Special Sterile Compounding Permit: Any pharmacy engaged in sterile compounding must obtain a special sterile compounding permit, except the following pharmacies:

(a) Stand alone Special Parenteral / Enteral pharmacies;
(b) Special Parenteral / Enteral Extended Scope Compounding pharmacies;
(c) Modified Class II B pharmacies engaged in the immediate use compounding in accordance with USP 797;
(d) Non-sterile compounding pharmacies.

Compounding Permit Application and Information," effective May 2013, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?NO=Ref-03143

Note to Committee Members: At this time Non-Resident Pharmacies and Federally Registered Outsourcing Facilities do not have to obtain this type of permit, but permitting of both may occur after the 2014 legislative session.

64B16-28.802 Special Sterile Compounding Permits.

With the exception of those pharmacies which hold an active stand alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, a special sterile compounding permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products. This permit is an additional permit required by a licensed pharmacy and shall not be considered a modifier. The compounding of sterile products must be in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16-27.797, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 6-18-13, Amended 10-20-13.

Suggested Changes:

A Special Sterile Compounding Permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products. This permit in an additional permit required by a licensed pharmacy and shall not be considered a modifier to any other type of pharmacy permit. The compounding of sterile products must be in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16.797, F.A.C.

The following pharmacies, which hold an active pharmacy permit, are not required to obtain a Special Sterile Compounding Permit:

(1) Stand alone Special Parenteral / Enteral pharmacies;
(2) Parenteral / Enteral Extended Scope Compounding pharmacies;
(3) Modified Class II B pharmacies engaged in the immediate-use compounding in accordance with USP 797; and
(4) Non-sterile compounding pharmacies.

64B16-27.700 Definition of Compounding.

"Compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term "commercially available products," as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

(a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

(b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.

(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy, except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

(3) Office use compounding, "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(d) The pharmacy and the practitioner enter into a written agreement. The agreement shall specifically provide:

1. That the compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity;

2. That the practitioner shall include on the patient's chart, medication order, or medication administration record the lot number and the beyond-use-date of any compounded drug administered to the patient that was provided by the pharmacy;

3. That the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded drugs.

(e) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of four (4) years and shall include:

1. The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;

2. The name, strength, and quantity of the compounded drug provided, including the number of containers and quantity in each;

3. The date the drug was compounded;

4. The date the compounded drug was provided to the practitioner;

5. The lot number and beyond use date.

(f) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:

1. The name, address, and phone number of the compounding pharmacy;

2. The name and strength of the preparation of a list of active ingredients and strengths;

3. The pharmacy's lot number and beyond-use-date;

4. The quantity or amount in the container;

5. The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and

6. The statement “For Institutional or Office Use Only – Not for Resale,” or if the drug is provided to a veterinarian the statement “Compounded Drug.”

Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.0155, 465.0265 FS. History–New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08, 3-21-13.

March 11, 2014

Ms. Tammy Collins
Acting Executive Director
Florida Department of Health
Board of Pharmacy
4052 Bald Cypress Way
Bin C04
Tallahassee, FL 32399-3254

Re: Rule No. 64B16-27.700 Definition of Compounding

Dear Ms. Collins:

Pfizer, Inc. (Pfizer) appreciates the opportunity to offer comments on Rule No. 64B16-27.700 Definition of Compounding. Pfizer is a research-based global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life for people around the world.

Pfizer recognizes that the state of Florida seeks to ensure the safety of compounded drugs while maintaining patient access to necessary medications. However, Pfizer believes that Florida's laws and regulations should be more aligned with federal provisions, especially in order to protect providers from violating federal laws.

Pfizer's key comments include recommendations for Florida compounding regulations, and note that the state's regulations should:

- mirror the federal definition of compounding.
- mirror federal law in prohibiting the compounding of drugs that are essentially copies of commercial drugs.
- prohibit the compounding of drugs which the federal Health and Human Services (HHS) Secretary has identified as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of the drug product, pursuant to the federal laws, regulations or guidance from the federal Food and Drug Administration (FDA).

To address each of these concerns, Pfizer offers the following comments for consideration:

I. Florida compounding regulations should mirror the federal law definition of compounding.

Pfizer believes it is important that state laws and regulations conform to federal requirements in order to better protect public health and safety as well as to avoid conflicts that may place providers at risk for state or federal violations. Toward that end, it is critical to maintain the historical distinction between valid compounding by pharmacists versus the manufacturing of new drugs in potential violation of the federal Food, Drug & Cosmetic Act (FD&C Act). We believe that distinction is properly maintained by the compounding provisions under the FD&C Act and that Florida has a unique opportunity to model its regulations to recently enacted changes in federal law.[1] The Drug Quality and Security Act (DQSA) provides for clarification and new controls on the compounding of drugs by pharmacies in the United States.

[1] Drug Quality and Security Act (H.R. 3204), enacted November 27, 2013.

For traditional compounding, federal law allows for the compounding of a drug when the drug is compounded for an identified individual patient based on a valid prescription order which indicates that a compounded product is necessary for the identified patient. Federal law also allows for the compounding of limited quantities before receipt of a prescription when the pharmacy has historically received prescriptions for a compounded drug and when the pharmacy has an established relationship with either the patient receiving the compounded drug or the prescriber.

Currently, Florida regulations include in its definition of compounding "*the preparation of drugs or devices in anticipation (emphasis added) of prescriptions based on routine, regularly observed prescribing patterns*" (64B16-27.700).

Pfizer is concerned that this definition is overly broad and allows for compounders to produce excessive quantities of drugs "in anticipation of prescriptions," without the necessary historical relationship with a patient or a prescriber, and thus, potentially crossing the line between compounding and manufacturing. As noted above, it is important to maintain this distinction because when this line is crossed, such "manufacturing" is done without compliance with provisions under the FD&C Act designed to protect public health and safety, such as the new drug requirements and the Good Manufacturing Practice regulations (GMPs). Instead, Pfizer recommends that Florida use language that conforms to the federal definition of compounding that includes some or all of the following language (21 U.S.C. 353a):

> *...a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—*
>
> *(1) is by—*
>
> *(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or*
>
> *(B) a licensed physician,*
>
> *on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or*
>
> *(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and*
>
> *(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—*
>
> *(i) the licensed pharmacist or licensed physician; and*
>
> *(ii) (I) such individual patient for whom the prescription order will be provided; or*
>
> *(II) the physician or other licensed practitioner who will write such prescription order.*

Additionally, Pfizer believes that it would be beneficial to define the term "limited quantities" to mean:

> *"No more than the quantity necessary to fill the number of prescriptions expected to be received for a one-week period based on a documented history of the receipt of such prescription orders for individual identified patients by the licensed pharmacist."*

This definition would be more consistent with the overall federal framework of traditional patient compounding where the history of prescription is tied to individual patients.

II. Florida compounding regulations should mirror federal law in prohibiting the compounding of drugs that are essentially copies of commercial drugs.

Federal law states that a drug product can only be compounded if the provider "*does not compound regularly or inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product" (21 U.S.C. 353a)*. This is contrary to 64B16-27.700(1)(c) which allows *"The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis…"*

Pfizer believes that Florida regulations should conform to federal regulations, otherwise pharmacies would be at risk for violating federal law regarding the manufacturing of unapproved generic drugs. Traditionally, compounding has been used to provide individualized drugs when commercially-produced drugs did not meet the health needs of a patient and to maintain access to drugs that may not have been commercially available due to drug shortages, unavailability, or discontinuation. Compounding continues to be used to address supply issues for drugs, however, providers should not be allowed to compound large amounts of drugs on a regular basis (which is essentially the manufacturing of unapproved drugs) if this product is already available commercially.

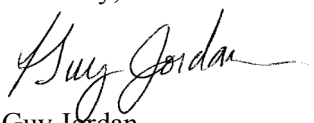
III. Florida compounding regulations should prohibit the compounding of drugs which the HHS Secretary has identified as demonstrably difficult to compound, pursuant to the federal compounding law.

Federal law states that providers can only compound drugs that include components of drugs approved by the Secretary of HHS, appear on a list of drugs developed by the Secretary of HHS, or do not appear on a list published by the Secretary of HHS of drug products that have been found to be unsafe or not effective (21 U.S.C. 353a).

Pfizer believes that Florida should prohibit the compounding of the same drugs which the Secretary of HHS has listed as prohibited for compounding. This helps eliminate any confusion a pharmacy may have between what is allowed pursuant to state and federal laws, and ensures that patients in Florida receive the same protections of the federal law, including that compounded drugs are safe, effective, and reviewed by the FDA and Secretary of HHS. The necessity of oversight on the safety of compounded drugs was evidenced by the 751 illnesses and 64 deaths associated with contaminated compounded steroid injections from a single pharmacy.[2]

Pfizer appreciates the opportunity to comment on the Definition of Compounding rule, and we welcome further discussion. Please do not hesitate to contact me if I can be of further assistance. We look forward to working with the Board of Pharmacy to improve access to safe compounded medicines for Floridians.

Sincerely,



Guy Jordan
Director, US Government Relations
Pfizer Inc. 9628 Deer Valley Drive, Tallahassee, FL 32312

[2] The Pew Charitable Trusts. U.S. Illnesses and Deaths Associated with Compounded Medications. September 5, 2013. Accessed 3/4/2014 online at: http://www.pewhealth.org/other-resource/us-illnesses-and-deaths-associated-with-compounded-medications-85899468587 .

National Association of Boards of Pharmacy®
Verified Pharmacy Practice[CM] Inspection Form

General Pharmacy Inspection

Business or Corporation:		Telephone number:		Date:		
Doing Business As (DBA):		Toll free number:		Start time:		
Address:		Fax number:		End time:		
City:		Pharmacist-in-Charge (PIC):				
State:		Zip:		Pharmacy/PIC email:		
Pharmacy website:				Inspector(s):		

Hours:	Sun	Mon	Tues	Wed	Thu	Fri	Sat
Open							
Close							

Licensure Information for State of Residence and Federal (DEA, FDA, etc.)

License/Registration Agency:	License/Registration Type or Category:	Business Name on License/Registration:	License/Registration Number:	Expiration Date:

Inspector Notes:

	Inspection Information	Y/N/?/NA	Note
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty in the Note.*		
2.00	Do prescribers or other health care providers link to the applicant's Web site or direct patients to the Web site or to this pharmacy? *If so, who?*		
3.00	Does the applicant list links to prescribers or clinics on its Web site? *If so, to whom?*		
4.00	Does the pharmacy have any other websites? *List other names/URLs.*		
5.00	Are photographs allowed during the inspection (no protected health information (PHI))?		
	Inspector Notes and list of others interviewed as part of the inspection:		

	Type(s) of practice Type "X" for all that apply				Facility Size in Square Feet		Personnel	
	Traditional retail		Mail Order (in-state)		Total Pharmacy:		Total Pharmacists:	
	HMO/PBM only		Mail Order (out-of-state)		Nonsterile Compounding Area		Total Technicians:	
	Institutional		Central Fill/Processing		Sterile Compounding Clean/Buffer Room		Total Interns or Students:	
	Closed Door		Patient Care Programs		Sterile Hazardous Clean/Buffer room:		Total Other Personnel:	
	Open to the Public		Nonsterile Compounding		Ante Room:		Number of Pharmacist Hours Per Week:	
	Provide products for 'Office Use'		Sterile Compounding		**Volume**		Number of Technician Hours Per Week:	
	Wholesale Distributor		Internet Pharmacy		Total Prescriptions Per Day Dispensed:		Total Compounding Pharmacists:	
	Manufacturer		Telepharmacy		Total Orders Per Day Distributed:		Total Compounding Technicians:	
	Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific.							

	Inspector Notes:

	Services	Y/N/?/NA	Note
6.00	Does the pharmacy provide delivery service to patients in this state? *Is delivery by an employee or by an outside service?*		
7.00	Does the pharmacy mail or send prescription products to patients in this state? *Indicate carriers that are used.*		
8.00	Does the pharmacy deliver, mail or send prescription products to patients in any other states? *View the mailing log. List other states in notes.*		
9.00	Does the pharmacy have a drive through window?		
10.00	Does the pharmacy dispense prescription products for veterinary use? *Indicate the approximate volume or percentage per month.*		
11.00	Does the pharmacy DISTRIBUTE prescription products for veterinary use? *Indicate the approximate volume or percentage per month.*		
	Inspector Notes:		

	General Operations and Licensure If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
12.00	Are pharmacy licenses, permits and registrations (state, controlled substance, Drug Enforcement Administration (DEA), etc.) posted in customers' view and current? *(Provide details if 'no'. Answer NA if closed door pharmacy)*		
13.00	If the pharmacy mails or delivers to patients out-of-state, does it have current licenses in all the states into which it sends prescription products? *List other states in which the pharmacy is licensed.*		
14.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection.*		

15.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*		
16.00	Does the pharmacy hold ANY wholesale, distributor or manufacturer licenses? *List the licenses in 'Note' and document information in the license grid above.*		
17.00	If the pharmacy distributes any compounded products to practitioners or facilities that are not patient specific, is it registered with the Food and Drug Administration (FDA)? *Indicate if it is registered as a manufacturer or an outsourcing facility, and document the registration in the license grid above. If it is NOT registered, indicate the exemption in the "Note".*		
18.00	Is the pharmacy licensed in any other state as a non-resident pharmacy? *List the states.*		
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If so, note the state and the date of the inspection.*		
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the exemption or restriction.*		
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the waiver or variance.*		
22.00	Has the pharmacy been inspected by DEA? *If so, indicate the inspection date and note any deficiencies.*		
23.00	Has the pharmacy been inspected by FDA? *If so, indicate the inspection date and note any deficiencies, significant correspondence, or if a '483' was issued.*		
24.00	Does the pharmacy hold any accreditations (DMEPOS, VIPPS, VAWD, Vet-VIPPS, PCAB, etc.)? *If so, indicate which in notes.*		
25.00	Has the pharmacy held any accreditations or certifications in the past that it no longer holds? *Provide a list and the reasons for discontinuation (such as expired, rescinded, etc.).*		
26.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc.? *If so, record the Clinical Laboratory Improvement Amendments (CLIA) waiver expiration date and the name of lab director listed. Verify that the lab director is current.*		
27.00	Does the pharmacy participate in the VFC (Vaccines for Children) program? *Note the date the pharmacy was inspected.*		

28.00	Does the pharmacy maintain any emergency kits in nursing homes, long term care facilities, or other entities? *Describe and verify the related policies and procedures (P&Ps) are in place.*		
29.00	Does the pharmacy maintain any automated prescription dispensing devices? *Describe and verify that the relevant P&Ps are in place.*		
	Inspector Notes:		

	Policy and Management **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
30.00	Are P&Ps available in the pharmacy? Are they in hard copy or electronic form?		
31.00	Do the P&Ps address the processing, compounding, dispensing, delivery, storage, and use of prescriptions products and include the handling of hazardous or infectious waste or spills?		
32.00	Are the P&Ps reviewed and updated regularly by the PIC? *Describe the procedure, including the review frequency and who performs the reviews.*		
33.00	Are systems in place for the on-going monitoring of state and federal laws/regulations for changes? *Give details of the system and resources or indicate if it is a corporate process.*		
34.00	Are resources and related training in place for pharmacy staff to apply changes in law/regulation into current practices? *How is training documented?*		
35.00	Is there a responsible member of management identified as the decision-maker when questions of law/regulation arise? *Record his or her name and title and the steps used to resolve a law question.*		
36.00	Is there a statement in the P&P or are other means used to ensure that the most stringent laws/regulations are followed? *Example: Syringes require a prescription in some states and not others.*		
37.00	Does the pharmacy have appropriate law references including state and federal regulations? *Indicate if they are hard copies or are available online, and verify that the pharmacy can access online regulations in all the states in which it is licensed (such as bookmarked).*		

38.00	Are Material Safety Data Sheets (MSDS) available to personnel for all drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*		
38.10	Does the pharmacy have a hazardous waste handling and collection system? *For example, empty bottles that contained chemotherapy medications or warfarin. Indicate how often the bin is emptied/collected and the vendor used.*		
39.00	Does the pharmacy have a clear organizational structure? *The pharmacy staff know who they report to and who the PIC reports to at corporate, if applicable.*		
40.00	Does the pharmacy have an annual budget and ongoing financial accounting information to track performance to the budget? *Indicate who develops the budget and if financial information is reviewed by a CPA or finance department.*		
41.00	Does the pharmacy have P&Ps for *handling partial fill prescriptions, returning prescriptions to stock if they are not dispensed including reversal of claims, and a "refill too soon" policy?*		
42.00	Are third party claims reconciliations performed and monitored, and are errors tracked? *Indicate if performed these are in-house, by corporate, or are contracted out.*		
43.00	Is there a formula or process to determine staffing hours for pharmacists and technicians? *If not, how is staffing determined?*		
44.00	Are patient care programs taken into account when determining staffing?		
45.00	Is there a mechanism for employees to anonymously report unethical, illegal, or compliance and safety concerns or issues? A p*rocedure in place for handling reports received, including investigations, corrective actions or disciplinary processes.*		
46.00	Does the pharmacy hold regular staff meetings? *How often?*		
47.00	Does the pharmacy have a document retention procedure? *How long are prescription files, invoices, inventory information, quality assurance (QA) data, etc. kept on file?*		
48.00	Are all pharmacy documents kept on site? *If not, where?*		
	Inspector Notes		

	Personnel **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
49.00	Are all pharmacists appropriately licensed or registered in this state and in good standing? *How is this verified and documented?*		
50.00	Are all technicians appropriately licensed, registered, or certified in this state and in good standing? *How is this verified and documented? (Enter "NA" if this is not required by the state)*		
51.00	Are pharmacists providing patient services that require additional training or certification appropriately trained and certified? *Are the certifications current? (Immunization, MTM, etc.)*		
52.00	Are the above pharmacist and technician credentials posted in customers' view and current?		
53.00	Does the PIC monitor all licenses to ensure they are current? *If not the PIC, who?*		
54.00	Are all personnel wearing nametags that clearly identify if they are a pharmacist or a technician? What about other positions?		
55.00	Does the pharmacy use relief personnel from outside agencies? *How are licenses, registrations, or certifications verified?*		
56.00	Does the pharmacy have a technician policy that specifies what a technician is allowed and not allowed to do?		
57.00	Do employees undergo a background check or drug testing? *Indicate which or both, and whether it is only upon hire or ongoing. Note if the pharmacy relies on checks performed by the board of pharmacy.*		
58.00	Are employees screened against the Office of the Inspector General (OIG) exclusion list? *Initially, ongoing, or both.*		
59.00	Is new hire training performed and documented? *View the documentation*		
60.00	Is on-going training performed and documented including HIPAA, OSHA blood borne pathogen or hazardous materials handling, and fraud, waste & abuse? *View the documentation.*		
61.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? *Teratogenicity, carcinogenicity, reproductive issues.*		

62.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, admin, clerks, etc.) who may have contact with hazardous drugs or chemicals of chemotherapy spill kit procedures and hazardous material handling?		
63.00	Is there a performance review process and is it documented?		
64.00	Is a procedure for corrective or disciplinary action in place and documented?		
	Inspector Notes		

	Facility and Security **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
65.00	Does the pharmacy have a security/alarm system in place with door alarms and motion detectors?		
66.00	Are alarm codes unique to the individual? *Is a report available to show after hours access and by whom?*		
67.00	Does the pharmacy have cameras? *How long are images kept?*		
68.00	Does anyone have access to the pharmacy (after hours) in the absence of the pharmacist? *Explain.*		
69.00	Do pharmacy staff remain in the pharmacy if the pharmacist is absent on a meal break? *If so, is there a policy regarding what activities may or may not be allowed during the pharmacist's absence?*		
70.00	Is entry to prescription product storage and processing areas limited to task critical employees?		
71.00	Are Schedule II controlled substances kept in a locked cabinet or safe? *Indicate if it is locked at all times and who has access.*		
72.00	Are there housekeeping standards to ensure the environment is professional, safe, neat, and clean?		
73.00	Is the pharmacy clean and is there appropriate space for the prescription volume? *Look for clutter or crowded counters or stacks of prescriptions to be checked.*		
74.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Indicate ratio used and the maximum number of staff who work at the same time.*		
75.00	How many feet (approximately) of free counter space (without computers or other equipment) at least 18 inches deep is available?		

76.00	Is there a heating and air conditioning system? Indicate which or both and if they are operational		
77.00	Is temperature in the drug storage area monitored? *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*		
78.00	Is humidity in the drug storage area monitored? *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*		
79.00	Is refrigerator temperature monitored 24/7? *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*		
80.00	Are the refrigerator and freezer restricted to drug products only (no food)?		
81.00	Is freezer temperature monitored 24/7? *Describe the process. Indicate range. How are excursions detected? How long are records maintained? (This is only required if the freezer is used to store products. Enter "NA" if used only for ice/cold packs)*		
82.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe processes*		
83.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes*		
84.00	Are there contingency plans in the event the pharmacy cannot be secured? *How will the drug products be handled?*		
85.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity if the products has been compromised?		
86.00	**Does the pharmacy utilize any automated apparatuses for prescription processing (such as robotics, Baker cells, etc.)? *List numbers and types.***		
87.00	• Are cleaning, calibration, and maintenance procedures performed on the apparatuses? *View logs*		
88.00	• Is there a procedure available that details who may fill the automated apparatuses, how filling accuracy is checked, and what documentation is kept?		
	Inspector Notes		

	Patient Counseling Areas If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
89.00	Are patients able to overhear staff conversations behind the counter? *Note your observations.*		
90.00	Are patients able to hear telephone conversations behind the counter? *Note your observations.*		
91.00	**Does the pharmacy have a private area for patient counseling and providing patient services?** Is the area:		
92.00	• of sufficient size and accommodations to comfortably seat at least three people (pharmacist, patient and caregiver) at a table?		
93.00	• meeting ADA criteria including wheelchair access?		
94.00	• private, so that when a typical patient is sitting or standing in the counseling area, the patient cannot be seen by others (including other patients, customers and employees)?		
95.00	• entirely devoted to enhancing patient outcomes and not used as a storage room for merchandise or other non-related items?		
96.00	• accessible to the patient without having to traverse through dispensing or storage areas?		
97.00	• enclosed sufficiently to prevent typical patient consultation conversation from being heard from other areas of the business?		
98.00	• enclosed sufficiently to prevent noise from other areas of the business to interfere with or distract from typical conversation in the consulting area?		
99.00	• equipped with access to a computer for patient files, documentation, and access to references during counseling or provision of patient care services?		
100.00	**Does the pharmacy use privacy panel areas at the counter for short consultations?**		
101.00	• Are the panels opaque and tall enough that a patient cannot be seen above them?		
102.00	• Are the panels sound-dulling (using fabric or acoustic material on the inside surfaces)?		
103.00	• Do the panels extend out past the patient so the patient steps into the 'booth' (at least 18 inches deep) to provide privacy from other customers?		
104.00	• Do the panels extend past the pharmacist (at least 18 inches) so that the pharmacist conversation is private from others at the counter and employees?		

105.00	• Is the paneled counseling area free from merchandise or other products not directly needed for the counseling?		
106.00	• Does the pharmacist have access to the computer and references while counseling the patient in the paneled area?		
107.00	• Does the paneled area open out to a main aisle or the patient waiting area?		
108.00	• Does the paneled area meet ADA criteria including wheelchair access? If not, how are these patients handled?		
109.00	**Does the pharmacy have a drive through window?**		
110.00	• Is counseling at the drive through window confidential from the patient side (outside)? *For example, a handset could be used, proximity to parking areas, etc.*		
111.00	• Is counseling at the drive through window confidential from the pharmacist side (inside)? *For example, a handset could be used, proximity to patient areas, etc. If no handset is used, verify that the speaker volume is not loud enough to be heard outside of the pharmacy.*		
112.00	• If the drive through window is not equipped for confidential counseling, is there signage or other indication that the conversation is not confidential?		
113.00	• Does the pharmacist have computer access while counseling at the drive through window?		
	Inspector Notes		

	Product Receipt and Inventory **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
114.00	Does the pharmacy restrict ordering to only approved wholesale distributors or manufacturers? *Indicate who approves suppliers and if licensure is verified.*		
115.00	Are orders generated and sent by the computer for prescription products including CIII-CV controlled substances?		
116.00	Who can alter the orders before they are sent?		
117.00	Does the pharmacy utilize paper DEA-222 forms to procure C-II substances? *Who on the staff has the authority (POA) to sign the DEA-222 forms?*		
118.00	Does the pharmacy utilize CSOS (electronic C-II ordering) to procure C-II substances?		

119.00	Is the receipt of C-II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification*		
120.00	Are invoices for controlled substances that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?		
121.00	Are orders sent/received every week day? *If not, how often are orders sent and received?*		
122.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*		
123.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe*		
124.00	**Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?**		
125.00	• Does the pharmacy purchase APIs directly from the manufacturer? *If not, indicate the source of APIs.*		
126.00	• Does the pharmacy verify that the source of the API is an FDA-registered facility? *How?*		
127.00	• Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources in the Note section.*		
128.00	Does the computer system track on-hand quantities of products? *Who can adjust the on-hand quantities and are adjustments tracked?*		
129.00	Does the computer track on-hand quantities of APIs used for compounding?		
130.00	Does the pharmacy keep a perpetual inventory log of CII controlled substances? *Does this include APIs?*		
131.00	Is the CII perpetual inventory log reconciled regularly? *Indicate how often CII controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*		
132.00	Does the pharmacy keep a perpetual inventory of any other products? *Indicate which in the Note section.*		
133.00	Does the pharmacy have a complete physical inventory of products performed at least once yearly? *If cycle counting, indicate the process.*		

134.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken - minimum every 2 years.*		
135.00	Does the pharmacy have any DEA-106 forms (theft or loss of controlled substances) on file? *Indicate how many in the last two (2) years.*		
136.00	Are events or discrepancies that are suspected to be due to criminal activity reported to the appropriate agency, if warranted?		
137.00	Are all products inspected upon receipt to detect any packaging issues, damage, etc.? *What happens if products are damaged?*		
138.00	How are outdated, damaged, or recalled products segregated? *How often does the pharmacy check for out-of-date products? Does it include over-the-counter (OTC) products?*		
139.00	Are expired or damaged products destroyed on-site? *View documentation. If not, note the name of the reverse distributor.*		
140.00	Does the pharmacy repackage bulk containers of prescription medications into smaller containers for ease of use? *Verify there is a P&P including labeling - what expiration date is on the repacked container?*		
141.00	Does the pharmacy pre-pack bulk containers of prescription medications into unit-of-use quantities? *Verify there is a P&P including labeling - what expiration date is on the pre-packed container?*		
142.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up? *Are the products returned to the bulk stock bottle or set on the shelf with the prescription label? Indicate expiration date given in the Note section.*		
	Inspector Notes		

	Prescription Processing **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
143.00	Are any portions of the prescription processing performed at a different location? *If so, explain. Is there a central fill/central processing agreement?*		
144.00	When a prescription is accepted to fill, is there a procedure to ensure the information is complete?		

145.00	Are adequate processes in place to assure the integrity, legitimacy and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*		
146.00	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*		
147.00	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe - do the processes include comparing the physical addresses of the patient and prescriber?*		
148.00	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both* .		
149.00	Does staff comply with applicable generic substitution and therapeutic substitution statutes and regulations?		
150.00	Does therapeutic substitution occur without patient or prescriber authorization?		
151.00	Are states' generic substitution formularies available? *Are staff familiar with the formularies?*		
152.00	Does the pharmacy system utilize bar code technology or other systems to improve accuracy and patient safety?		
153.00	Is the pharmacy computer system provided routine maintenance and is the information backed up? *Indicate the frequency of backup and if the backup data is stored offsite.*		
154.00	Is there a continuity plan should the system become inoperable? *How will data be retrieved?*		
	Inspector Notes		

	Patient Profiles If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
	Verify the following six bullets by viewing of a minimum 3 patient profiles (select from filled prescriptions to ensure current patients) to determine where the information is documented, that it's retrievable for drug utilization reviews (DURs), and that the information is gathered (the fields are not empty).		
155.00	• Does the patient information gathered include patient contact information, age or date of birth and gender?		
156.00	• Does patient information gathered include disease states or conditions (including pregnancy or breastfeeding information)?		
157.00	• Is allergy and sensitivity information obtained?		
158.00	• Is a complete medication history obtained including medications filled by other pharmacies or by mail order, samples, or medications administered at the clinic or hospital? *Note: a PBM/HMO closed door pharmacy that relies solely on claims data does not constitute a complete medication history as prescriptions for which the patient paid cash such as $4 generics are not recorded.*		
159.00	• Does the medication history include information on vitamins, herbal products, and other OTC products used?		
160.00	• Does the patient profile allow for the pharmacist's relevant comments or notes?		
161.00	Does the pharmacy have access to patients' Electronic Health Record (EHR)? *Provide detail regarding the type of information accessed such as lab values or clinical notes, etc.*		
162.00	Does the pharmacy access state PMP/PDMP program data? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*		
163.00	Is patient information updated regularly and routinely? Are patients or providers routinely asked if there are changes in disease states, allergy information, or medication use? *How often?*		
164.00	Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver?		

165.00	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include species, sex, breed or size, and the age of the animal? *How is it indicated in the computer system that the patient is an animal?*		
166.00	If the pharmacy dispenses veterinary prescriptions, does the pharmacy determine if the animal will be used for consumption (including eggs, milk, or meat)? *What references are used to provide the veterinary customer with wash-out periods for certain medications?*		
	Inspector Notes		

	Drug Utilization Review (DUR) **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
167.00	Does staff conduct prospective DUR prior to the dispensing of a medication or product? *At what point in the process does the DUR take place?*		
168.00	Is the DUR performed by the computer (the drug database is integrated into the prescription processing software)? *If not, describe how the DUR is performed.*		
169.00	Is the computer DUR database routinely updated and tested? *Provide details on how often the database is updated and how the pharmacy tests the updates.*		
170.00	Does the DUR include: • drug-drug interaction (Rx and OTC) • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse) • disease state or condition contraindication, • Incorrect dosage or duration of therapy • gender or age related contraindications *Indicate if there are other parameters routinely included in the DUR*		
171.00	Does the DUR include screening against OTC, herbal, vitamin products and medications not filled at this pharmacy? *Is this performed by the computer (has fields to enter this information) or is it performed manually by reading notes in the profile?*		

172.00	Does the pharmacy have references on hand for: pharmacology, dosage and toxicology, general patient reference, OTC products? *List in the Note section and indicate if they are in hard copy or electronic form.*		
173.00	Does the pharmacy have references on hand for any special demographics of its patient population or complementary medicine such as pediatrics, geriatrics, homeopathic, natural and herbal medicines, as appropriate? *List in the Note section and indicate if they are in hard copy or electronic form.*		
174.00	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database or compendium? *List and note if it is hard copy or electronic.* How does the pharmacy perform a DUR? (*There is no veterinary drug database that is integrated into pharmacy processing software to perform electronic DURs at this time so DUR must be performed manually)*		
175.00	Are DUR overrides/bypasses documented? *Indicate if documentation is via a password/biometric override or by computer logs* . Or if it is a manual system, are DUR issues noted and action documented?		
	Inspector Notes		

	Patient Counseling and Communication **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
176.00	Do pharmacists provide counseling for all first fill prescriptions? *Is the counseling performed proactively or may a clerk or technician extend the "offer to counsel"?*		
177.00	Do pharmacists provide counseling for all refilled prescriptions? *Is the counseling performed proactively or may a clerk or technician extend the "offer to counsel"?*		
178.00	Do pharmacists provide counseling on refilled prescriptions if there is a change in therapy or other issue determined by the pharmacist? *Is the counseling performed proactively or may a clerk or technician extend the 'offer to counsel'?*		
179.00	Is patient counseling provided for delivered prescriptions? *How?*		
180.00	Is patient counseling provided for mailed prescriptions? *How?*		
181.00	Are patients contacted for counseling when the prescription is picked up by someone other than the patient or caregiver (such as when a neighbor picks up the prescription)?		

182.00	Does patient counseling meet OBRA90 standards (appropriate medication use, storage, what to do for a missed dose, side effects, etc.)?		
183.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?		
184.00	Do pharmacists provide training to the patient or caregiver on any equipment provided? *Such as blood glucose meters, walkers, etc.*		
185.00	Do patient/caregiver training programs include a hands-on and reverse demonstration with actual items that the patient or caregiver is expected to use with parenteral products and/or compounded preparations such as special containers, administration equipment and devices?		
186.00	Are patient package inserts (PPIs) and printed drug information sheets provided to patients? *How?*		
187.00	Are MedGuides provided on every fill and refill of medications for which they are required? *How?*		
188.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin or Tikosyn)*		
189.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products? *How?*		
190.00	Do patients receive instruction and directions on reporting any adverse reaction or event?		
191.00	For compounding: Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?		
192.00	Are patients or caregivers encouraged to contact the pharmacy if they have any questions or would like more information? *How?*		
193.00	Does the pharmacy provide any follow-up to new prescriptions? *Such as patient calls three days after antibiotic pick-up.*		
194.00	Do patients and other customers have access to pharmacists or interns for other questions including general health and OTC questions?		
195.00	Does the pharmacy have a process to address communication needs with regard to the patient's level of understanding? *Literacy, health literacy, education level, etc.*		

196.00	Does the pharmacy have a process to address communication needs with regard to language and cultural influences? *Provide details of language issues including cultural training*		
197.00	Does the pharmacy have a process to address communication needs with regard to disabilities such as blindness, deafness, or other barriers to communication? *Explain.*		
198.00	Is patient counseling documented? *Is it just "yes or no" that counseling is provided or does it include content?*		
199.00	Is the pharmacist able to make pertinent notes in the profile of the patient during counseling?		
200.00	Is refusal of counseling documented? *How? Is a reason recorded?*		
201.00	Does the pharmacy provide information and resources to patients and the public in other formats such as internet live chat, Web site information or links, etc.?		
202.00	Do patients have 24-hour access to a pharmacist? *How?* *(If no, enter "NA" for the next three questions)*		
203.00	• Do after hours pharmacists have access to patient files? *How?*		
204.00	• Do after hours pharmacists have access to references? *What are they?*		
205.00	• Are after hours consultations documented? *How?*		
206.00	Does the after-hours voicemail message have instructions on who to contact based on urgency of issue? *For example, if this is an emergency please dial 911; leave message if not urgent; alternative number to call for advice after hours such as a nurse line, etc.)*		
207.00	Are adequate processes in place for contacting the patient/caregiver and prescriber if an undue delay is encountered in delivering a prescribed drug? *What is the process when the pharmacy receives a prescription for a product not in stock? Not available in the marketplace?*		
208.00	Does staff transfer prescriptions to other pharmacies? *What triggers a transfer?*		
209.00	Are adequate processes in place to inform patients or caregivers about drug recalls depending on the type or level or recall? *Who contacts the patient (pharmacist, technician, customer service)?*		

210.00	Are adequate mechanisms in place to educate patients and caregivers about the appropriate means to dispose of expired, damaged, and unusable medications (including patches, syringes, and other drug administration equipment and supplies)? *What is the source for the disposal information? (FDA? Other?)*		
211.00	Does the pharmacy take prescription returns for redispensing? *If yes, describe program.*		
212.00	Does the pharmacy participate in a prescription drug take back program? *If yes, describe program.*		
213.00	Does the pharmacy participate in a needle exchange or similar program to supply clean needles and syringes? *If yes, describe program.*		
	Inspector Notes		

	Patient Confidentiality **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
214.00	Is the PIC also the HIPAA Privacy Officer? *If not, indicate privacy officer in Note.*		
215.00	Is there a HIPAA policy in place for employees, vendors, and contractors?		
216.00	Is the HIPAA-mandated Notice of Privacy Practices (NPP) been made available for patients? *How? For mailed/delivered prescriptions?*		
217.00	How is NPP receipt acknowledgement obtained? Signature stored electronically or hard copy? *How is this performed for prescriptions that are mailed or delivered?*		
218.00	Do employees deemed nonessential to patient care have access to confidential patient information? *Such as delivery services, non-pharmacy store management, etc.*		
219.00	Is access to the pharmacy system limited to appropriate personnel? *Password protected, access limited by job type, access revoked as appropriate such as upon termination, access to patient information in the computer is tracked*		
220.00	Are confidential documents shredded? *In-house or by a service?*		
221.00	Does the pharmacy appropriately destroy labeled prescription vials?		

222.00	Does the crisis plan includes security of paper and electronic patient information?		
	Inspector Notes		

	Prescription Receipt, Packing, and Transporting **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
223.00	Does the patient sign for prescriptions when they are picked up? *Manual or Electronic?*		
224.00	Does the patient sign for prescriptions obtained at the drive through? *Manual or electronic?*		
225.00	Does the pharmacy obtain signatures for prescriptions that are mailed or shipped? *How?*		
226.00	Are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?		
227.00	Does the pharmacy have testing data from the packaging supplier to confirm? *View documentation*		
228.00	Does the pharmacy conduct its own testing of packing materials? *View documentation, ensure includes both high and low temperature extremes.*		
229.00	Does the pharmacy obtain information from carriers regarding shipping conditions to maintain appropriate temperatures of the products? *Indicate carriers used.*		
230.00	Is the packaging tamper evident?		
231.00	Are the packages appropriately labeled if they contain hazardous materials?		
232.00	Does the pharmacy ship overnight?		
233.00	Do shipments go out on Fridays or weekends where they might sit in a truck for a period of time?		
	Inspector Notes		

	Patient Care Services If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
234.00	Does the pharmacy perform MTM - targeted medication reviews? *Is there a P&P available?*		
235.00	Does the pharmacy perform MTM – CMR (Comprehensive Medication Review)? *Is there a P&P available?*		
236.00	Does the pharmacy perform any Health and Wellness Screenings such as: blood pressure screening, cholesterol screening, osteoporosis screening? *Is there a P&P available? Is a CLIA waiver posted, if applicable?*		
237.00	Does the pharmacy provide any health and wellness programs such as: smoking cessation program, weight loss program. *Is there a P&P available?*		
238.00	Does the pharmacy send refill reminders or have an automatic fill program? *Is there a P&P available? Do customers sign up for program?*		
239.00	Does that pharmacy provide any adherence programs? *Program is patient specific with follow-up by pharmacy . Is there a P&P available?*		
240.00	Does the pharmacy provide patients with medications in blister packs or cards (such as nursing home patients)? *Is there a P&P available?*		
241.00	Does the pharmacy provide patients with medications in compliance packaging (where medications are grouped by time of day -- all morning meds in one pack, noon meds in another etc.)? *Is there a P&P available?*		
242.00	Does the pharmacy provide any medication synchronization services (to time all medications to come due for refill on the same date)? *Is there a P&P available?*		
243.00	Does the pharmacy provide an immunization program? List immunizations or vaccines provided at this pharmacy. *Is there a P&P available including emergency protocol?*		
244.00	Does the pharmacy have a care transition program? *Is there a P&P available?*		
245.00	Does the pharmacy provide any chronic disease education programs? *If yes, list in notes. Is there a P&P available?*		
246.00	Does the pharmacy provide any chronic disease management programs? *If yes, list in notes. Is there a P&P available?*		

247.00	Does the pharmacy participate in any collaborative practice agreements? *View agreements, verify they contain signatures of provider(s) and pharmacists(s). Is there a P&P available?*		
248.00	Does this pharmacy participate in pharmacist prescribing? *If so, under what circumstances? Is there a P&P available?*		
	Inspector Notes		

	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
249.00	Is there a documented Quality Assurance/Quality Improvement (QA/QI) program? *Who oversees the program?*		
250.00	Is QA data kept on site? If not, where? *Indicate if documents are kept electronically using software, using an on-line program, or in paper files.*		
251.00	Is QRE (Quality Related Event) defined? May a*lso be referred to as "incidents" or "errors".*		
252.00	Is there a form to fill out for a QRE? *Indicate if paper or electronic and who fills it out.*		
253.00	Are QREs reported to the board of pharmacy? *If not reported to the Board, indicate how long the files are kept.*		
254.00	Are QREs reported to an outside peer review committee or patient safety organization? *If so, indicate the name of the organization.*		
255.00	Are external errors documented and tracked? *View example documentation*		
256.00	Are internal errors documented and tracked? *View example documentation*		
257.00	Does staff document and report ADRs? *To FDA's MedWatch program or VAERS for immunizations? View example documentation*		
258.00	Are incidents involving malfunctioning or defective equipment documented and reported to the manufacturer or distributor? *View example of documentation*		
259.00	For compounded products: Are adverse events and defects with compounded products reported to FDA's MedWatch and to USP's MEDMARX programs?		

260.00	For compounded products: Does the QA program measure all aspects of the preparation and dispensing of compounded products including environmental testing, validation results, etc.?		
261.00	For compounded products: Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded?		
262.00	For compounded products: Are deficiencies in compounding, labeling, packaging, and quality testing and inspection identified and corrected?		
263.00	Are complaints documented and tracked? *Note if response time is tracked.*		
264.00	Are reports of contamination or instability of compounded preparations documented, investigated, and tracked? *Is there a recall system in place?*		
265.00	Are patient satisfaction surveys distributed and responses tracked? *Are the surveys pharmacy specific?*		
266.00	Are pharmacy information systems and technology performance issues measured and tracked? *Automated counting or dispensing apparatuses, computers, etc.*		
267.00	What other measurements are tracked and analyzed?		
268.00	Is data evaluated? *How often and by whom?*		
269.00	Is a root cause analysis process implemented?		
270.00	Is data trended over time (e.g., against previous years' data)?		
271.00	Is summary QA/QI report or data shared with staff?		
272.00	Are quality self-audits performed or internal peer-review staff meetings held and documented?		
273.00	Have process or policy changes or improvements been made based upon other data collected in the QA/QI program? *Provide example*		
274.00	Are these improvements or changes evaluated for performance as a way to measure the effectiveness of the CQI program?		
	Inspector Notes		

National Association of Boards of Pharmacy
Verified Pharmacy Practice[CM] Inspection – Supplemental Form

Nonsterile Compounding USP Chapter <795> Supplement to the General Inspection

	Business or Corporation:	0		Telephone number:	-	Date:	1/0/1900
	Doing Business As (DBA):	0		Toll free number:	-	Start time:	0:00
	Address:	0		Fax number:	-	End time:	0:00
	City:	0		Pharmacist-in-Charge (PIC):	0		
	State:	0	Zip: 0	Pharmacy/PIC email:	0		

	General Administrative	Y/N/?/NA	Note
1.00	Are non-sterile compounded products for Office Use or DISTRIBUTION listed with the FDA? *Indicate if they have their own NDC numbers and the facility identifier.*		
2.00	Does the pharmacy have employees or contract personnel who act as representatives (for example sales forces) for the non-sterile compounded preparations? *If so, indicate if they provide samples of products. Provide a list of these samples.*		
3.00	Does the pharmacy have specific references for non-sterile compounding? *List and indicate if they are in hard copy or electronic format.*		
	Inspector Notes:		

	Product Mix by Volume or Percent (note volume/frequency or % in cell or inspector Notes)	Human	Veterinary	Dispensed total	Dispensed controlled substances	Distributed total	Distributed controlled substances	Hazardous Drugs
	Non sterile compounded product total							
	Non sterile compounded product - Simple							
	Non sterile compounded product - Moderate							
	Non sterile compounded product - Complex							
	Other special:							
	Inspector Notes:							

	General Operations ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
4.00	Does the pharmacy dispense non-sterile compounded preparations pursuant to a prescription? *View record for legitimate prescription including a complete patient profile (allergies, disease states, other prescriptions and over the counter meds taken, etc.) and DUR performed. Watch for "list" of patients where the compounded preparation is delivered to the practitioner and no patient profile kept and no DUR performed.*		
5.00	Does the pharmacy distribute non-sterile compounded preparations to practitioners for office use?		
6.00	Does the pharmacy distribute non-sterile compounded preparations to hospitals, clinics, or surgery centers?		
7.00	Does the pharmacy provide non-sterile compounded preparations to other pharmacies for dispensing? *If so, does the pharmacy have central fill contracts with these pharmacies for patient specific preparations or do they provide non-patient specific compounded preparations to other pharmacies?*		
8.00	If the pharmacy compounds non-sterile preparations for animals, does the compounding meet the same standards as compounding for human patients?		
9.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Indicate which in notes*		
10.00	Does the pharmacy compound topicals (creams, ointments, inserts, suppositories, patches, sprays, etc.)? *Indicate which in notes*		
11.00	Does the pharmacy compound radiopharmaceuticals?		
12.00	Does the pharmacy compound vitamin or nutritional supplements?		
13.00	Does the pharmacy make a copy of an approved product? *Indicate under what circumstances and how it is documented. For example, product is in short supply as verified on FDA Web site.* Indicate volume or percent compounded currently in note.		

14.00	Are products to be compounded appropriately identified as **simple?** 1. *Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s.* *2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.*		
15.00	Are products to be compounded appropriately identified as **moderate?** 1. *Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units.* *2. Making a preparation for which stability data for that specific formula is not available.*		
16.00	Are products to be compounded appropriately identified as **complex?** 1. *Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.*		
17.00	Are products to be compounded appropriately identified as **hazardous**? *National Institute for Occupational Safety and Health (NIOSH) list of drugs. Hazardous drugs exhibit: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low dose, or genotoxicity--includes hormone powders, chemotherapy, etc.*		
18.00	Does the pharmacist perform an evaluation of the dose, safety and intended use if the preparation to be compounded?		
19.00	For animal compounding, is the pharmacist knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used?		
20.00	For animal compounding, is it determined and documented if the animal is used for food (meat, milk, eggs, etc.)? *Or that the animal is a pet?*		
21.00	For animal compounding, is the pharmacist familiar with drug residues in the food chain and withdrawal times? *How?*		
22.00	For animal compounding, is the pharmacist familiar with regulations regarding drug use in performance animals? *How?*		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	Component Selection and Use *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
23.00	**Does the pharmacy make any compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?**		
24.00	Are certificates of analysis (COAs) obtained for all APIs? *Are COAs domestic or foreign in origin? Select several products from the shelf and ask to see the COAs for those products.*		
25.00	Does the pharmacy perform any testing/analysis of APIs? *If so, indicate how API is selected for testing, what tests are performed and if tested in-house or sent to an outside lab - indicate lab in notes.*		
26.00	If the source is a foreign FDA facility, does the pharmacy obtain information on the last FDA inspection of that facility and a copy of the report?		
27.00	Are USP- or NF-grade substances used, if available?		
28.00	If compendial quality components are not available, are chemically pure, analytical reagent grade or American Chemical Society-certified components used? *How is it determined the products are free from impurities that raise human or animal safety concerns?*		
29.00	Are other means used to establish purity and safety? *Describe the means, such as* lot *analysis, manufacturer reputation, reliability of source.*		
30.00	Examine the labeling on the APIs. Do any of the labels state "For Research Purposes Only" or "Not for Drug Use" or "Veterinary Use only" or similar? Or have non-standard labels (such as handwritten or from another pharmacy)? *If so, view invoices and record the source of these items and photos. Indicate how vet use only products are segregated to prevent them from being used for preparations compounded for humans.*		
31.00	Do all substances and components have a complete label including a batch control or lot number, and an expiration date?		
32.00	For substances without an expiration date assigned by the manufacturer or supplier, does the pharmacy have a procedure to assign a conservative expiration date and is it followed? *Containers labeled with date of receipt and the expiration date assigned is not greater than three (3) years, is supported with data and/or testing, and takes into consideration the nature of the component, its degradation mechanism, the container in which it's packaged, and the storage conditions.*		
33.00	Are all APIs labeled with the date they were received?		

34.00	Does the pharmacy repackage APIs into smaller containers for ease of use? *If so, how is the expiration date determined for the repackaged product?*		
35.00	Are bulk component containers labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels and are hazardous substances segregated?		
36.00	When manufactured products are used for compounding, do the labels contain a lot number and expiration date?		
37.00	When manufactured products are used for compounding, are all the other excipients in the product considered relative to the use, effectiveness, and stability of the compounded preparation to be made?		
38.00	Are any preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons? *How does the pharmacy determine this?*		
39.00	If compounding for food producing animals, does the compounder have a list of components prohibited for use?		
40.00	If components are used that are derived from ruminant animals (cow, sheep, goat) does the pharmacy obtain documentation that the component is in compliance with federal laws governing processing, use, and importation? *(the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist)*		
41.00	Do the ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards? *If not, how have the ingredients been determined to meet food-grade quality?*		
42.00	Where water is an ingredient, is purified or distilled water used?		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**

	Inspector Notes:

	BEYOND USE DATING (BUD) *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
43.00	Are BUDs assigned from the day of preparation?		
44.00	Are BUDs for nonaqueous formulations not later than the remaining time until the earliest expiration date of any API and not later than six (6) months?		
45.00	Are BUDs for water-containing oral formulations not later than 14 days when stored at controlled cold temperatures (refrigerated)?		
46.00	Are BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days?		
47.00	Are BUDs assigned based on dispensing in tight, light-resistant containers?		
48.00	Are any extended BUDs assigned? *Provide a list of products with extended BUD and how justified.*		
49.00	Is any testing done to support the extended BUDs? *Provide a list of products tested and the results of such testing.*		
50.00	Are any extended BUDs assigned greater than six (6) months from the date of compounding?		
51.00	When using a manufactured product as the active ingredient, is the expiration date of the manufactured product used as the BUD?		
52.00	Are appropriate microbiological preservatives (bacteria, yeast, and mold) used? *If not, why not and are products refrigerated?*		
53.00	Are any other processes used to sterilize preservative free products? *List types and ensure procedures include validation of the process.*		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**

Inspector Notes:

	Environment ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
54.00	Is the non-sterile compounding area a controlled environment and separate from the general pharmacy?		
55.00	Is there sufficient space available for the type and amount of compounding performed?		
56.00	Is entry into the non-sterile compounding area limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?		
57.00	Is only one preparation compounded at a time?		
58.00	Is the space orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations?		
59.00	Are procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions?		
60.00	Is the compounding area well lit?		
61.00	Are heating, ventilation, and air conditioning systems controlled to maintain the integrity of components, chemicals and reduce risk of contamination?		
62.00	Does the pharmacy perform non-sterile compounding using a powder hood or isolator? *If so, indicate models and types of equipment used.*		
63.00	Is appropriate protective attire (gowns, gloves, masks, etc.) available?		
64.00	Is there a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels?		
65.00	Is there adequate space to wash equipment and utensils including access to purified water for rinsing?		
66.00	Does the sterile compounding area have a fan? *View placement and indicate if the airflow affects disbursement of drug residue or contaminants*		

67.00	Are both the temperature and humidity monitored 24/7 in the compounding areas? *View documentation.*		
68.00	Are there alarms or alerts when excursions are detected in the compounding area? *Is there an action plan when an excursion occurs?*		
69.00	Is the bulk component storage area adequately arranged and maintained in a clean and sanitary condition?		
70.00	Are both the temperature and humidity monitored 24/7 in the bulk component storage areas (if separate from the compounding area)? *View documentation.*		
71.00	Are there alarms or alerts when excursions are detected in the bulk component storage area? *Is there an action plan when an excursion occurs?*		
72.00	Are hazardous drugs appropriately identified and marked, received, handled and stored by appropriately trained personnel? (OSHA regulations and NIOSH Alerts)		
73.00	Are all components, equipment, and containers stored off the floor and handled and stored to prevent contamination?		
74.00	Are all components and packaging containers and closures properly rotated to use oldest first?		
75.00	Is trash disposed of in a safe, sanitary, and timely manner including hazardous waste? *How is hazardous waste disposed of?*		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	TRAINING ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
76.00	Are pharmacists and technicians performing compounding appropriately trained and certified? *View documentation of training.*		
77.00	Does the training include cleaning and disinfection, garb, manipulation of ingredients including quality testing, labeling, and hazardous material handling?		

78.00	Does the training process for the preparation of compounds include demonstration of the compounding procedure first followed by the trainee performing the procedure under supervision successfully before allowed to perform compounding?		
79.00	Does training include the operation of any equipment that may be used when preparing compounded products? *Documentation needs to include training on operation, troubleshooting, and annual competency evaluation.*		
80.00	Are employees performing non-sterile compounding evaluated at least annually (including hazardous drug handling) and is the evaluation documented?		
81.00	Does the pharmacy use relief personnel from outside agencies to perform non-sterile compounding? *How are training and certifications verified? View documentation.*		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	COMPOUNDING EQUIPMENT ***If any part of a question is no, answer the whole question "no" and explain the observation.***	**Y/N/?/NA**	**Note**
82.00	Is the appropriate equipment available and in good working order? *View maintenance and calibration logs.*		
83.00	Is all equipment inspected for cleanliness and proper function prior to each use?		
84.00	Is all equipment thoroughly cleaned promptly after each use to prevent cross contamination? *Equipment and utensils washed using potable water with a soap or detergent, rinsing with* ***purified*** *water.*		
85.00	Does the pharmacy use separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products?		
86.00	If not, are there detailed procedures for meticulous cleaning of the equipment used for allergenic, cytotoxic, or hazardous ingredients immediately after use? *Including personnel performing cleaning are appropriately garbed?*		
87.00	If disposable equipment or supplies are used, are they disposed of appropriately?		

88.00	Are scales, balances, or other equipment used for measurement validated and calibrated at least annually?		
89.00	If a powder hood is used, has it been certified? How often? *Review copy of certification report.*		
90.00	If biological safety cabinet (BSC), compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI) hoods are used for hazardous substances, have they been certified? How often? *View copy of certification report. NOTE: If compounding with hazardous materials that are volatile, must use BSC or CACI only, and the cabinet must be vented to the outside.*		
91.00	If the hoods or isolators are located in a closed, controlled room environment, has the room been certified or tested? *View copy of report or testing results*		
92.00	If the hoods or isolators are not located in a closed, controlled room environment, is there documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel?		
93.00	Is there any environmental testing performed to detect contamination by drug residue in the pharmacy areas or areas served by the same ventilation system? *Drug residue may cause cross contamination to other products and expose staff. Not required but is recommended if compounding with hazardous materials, not using a hood, or compounding room not segregated.*		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	DOCUMENTATION ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
94.00	Does the pharmacy create a master formulation record the first time before compounding a new preparation? *Who reviews/approves?*		
95.00	Is every formulation evaluated for incompatibilities and the potential for an ineffective or toxic preparation? *How?*		

96.00	Does the master formulation record contain: 1. Official or assigned name, strength, and dosage form 2. All necessary calculations 3. Description of all ingredients and their quantities 4. Compatibility and stability information including references (when available) 5. Equipment used for the preparation 6. Mixing instructions to include order of mixing, temperatures, duration of mixing, and other pertinent factors 7. Container used and packaging requirements 8. Assigned BUD information 9. Labeling information including the generic name of and quantity or concentration of each active ingredient 10. Description of the finished preparation 11. Storage requirements 12. Quality control procedures and expected results		
97.00	Does the pharmacy create a compounding record for each compound prepared?		
98.00	Does the compounding record include: 1. Official or assigned name, strength and dosage of the preparation 2. Master Formulation Record reference 3. Sources, lot numbers, and expiration dates of all components 4. Total quantity or number of dosage units compounded 5. Person compounding the preparation 6. Person performing the quality control procedures 7. Person who approved the preparation 8. Date of compounding 9. Assigned internal identification number or prescription number 10. Description of the final preparation 11. Assigned BUD 12. Duplicate label 13. Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)? 14. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate		

99.00	Are all records kept for the length of time specified by the state? *Indicate how long records are kept and where.*					
		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	COMPOUNDING PROCEDURES ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
100.00	Have the Master Formulation Record and the Compounding Record been reviewed by the compounder to ensure it is error free?		
101.00	Do compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality? *How?* Does this include a unit-by-unit physical inspection of the products?		
102.00	Do the containers and closures selected meet USP standards (from container supplier)?		
103.00	Is container selection determined by physical and chemical properties of the preparation?		
104.00	Do compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed?		
105.00	Do personnel don appropriate protective garb when performing compounding? *Indicate any garb used: including if gloves only, gloves always or sometimes, gloves plus gown, mask, etc.*		
106.00	Are routine compounding procedures for batch preparation completed and verified according to written procedures? Including: Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly		
107.00	Are procedures for in-process checks followed? *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product and documentation of the compounding accuracy is by someone other than the compounder to ensure proper measurement, reconstitution and component usage.*		

108.00	If there are any deviations from the master formulation record, are these deviations recorded? *Is it determined if the deviation will affect the BUD?*		
109.00	Is there a plan for cleaning? *After each preparation, daily tasks, monthly tasks, etc.*		
110.00	Are personnel appropriately garbed for protection when cleaning?		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**

	Inspector Notes:

	FINISHED PREPARATION RELEASE CHECKS AND TESTS ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
111.00	Is the finished preparation observed to appear as expected in the master formulation record and documented?		
112.00	As appropriate, is the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength? Is it documented?		
113.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity?		
114.00	Is there a process in place to sample prepared products for potency and/or contamination? *Required if using extended BUD.*		
115.00	Does testing include physical, chemical, and microbiological characteristics?		
116.00	Are all products produced in batches tested? *Required if using extended BUD.*		
117.00	If any failed tests or discrepancies are observed, is there an investigation and are appropriate corrective actions taken before dispensing to patient?		
118.00	Are any products that are being tested dispensed or distributed before the test results are obtained? *If so, what is the procedure for recall if the test results indicate an issue?*		
119.00	Does the pharmacy have its own lab to perform testing? *If so, what testing is performed in house?*		

120.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what tests are performed.*		
121.00	Are there appropriate control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations? *Validation of equipment and personnel performance documentation*		
122.00	Do labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials?		
123.00	Are batch preparations (in anticipation of prescriptions) of an appropriate volume? *Are batch products in stock all within their BUD (not outdated)?*		
124.00	Do labels on patient-specific containers, in addition to standard label requirements, also include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials?		
125.00	Do labels on compounded preparations for food producing animals contain information regarding withdrawal times?		
126.00	Are preparations stored properly prior to dispensing based upon conditions upon which BUD was assigned?		
127.00	Are preparations examined immediately after preparation AND again immediately prior to dispensing for any signs of instability?		
128.00	If problems occur during compounding of an official USP monograph preparation, is it reported to USP?		
129.00	Are all issues that are reported to the pharmacy (adverse events, instability, etc.) documented, investigated, and corrective action taken?		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

The information and comments obtained in the supplement sections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

National Association of Boards of Pharmacy
Verified Pharmacy Practice[CM] Inspection – Supplemental Form

Sterile Compounding USP Chapter <797> Supplement to the General Inspection

	Business or Corporation:	0	Telephone number:	-	Date:	1/0/1900
	Doing Business As (DBA):	0	Toll free number:	-	Start time:	0:00
	Address:	0	Fax number:	-	End time:	0:00
	City:	0	Pharmacist-in-Charge (PIC):	0		
	State:	0 Zip: 0	Pharmacy/PIC email:	0		

	General Administrative	Y/N/?/NA	Note
1.00	Are sterile compounded preparations for Office Use or DISTRIBUTION listed with the FDA? *Indicate if they have their own NDC numbers and the facility identifier.*		
2.00	Does the pharmacy have employees or contract personnel who act as representatives (for example sales forces) for sterile compounded preparations? *If so, indicate if they provide samples of products. Provide a list of these samples.*		
3.00	Does the pharmacy have appropriate compounding references including USP Chapter 797, injectable drug compatibility, hazardous materials references? List references and indicate if they are in hard copy or electronic format.		
	Inspector Notes:		

	Product Mix by Volume or Percent (note volume/frequency or % in cell or Inspector Notes)	Human	Veterinary	Dispensed Total	Dispensed Controlled Substances	Distributed Total	Distributed Controlled Substances	Hazardous Drugs
	Total compounded sterile product							
	Compounded sterile product – low risk							
	Compounded sterile product – medium risk							
	Compounded sterile product – high risk							
	Compounded sterile product – immediate use							
	Compounded sterile **suspensions** for injection							

	Inspector Notes:

	General Operations *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
4.00	Does the pharmacy dispense sterile compounded preparations pursuant to a prescription? *View record for legitimate prescription including a complete patient profile (allergies, disease states, other prescriptions and over the counter meds taken, etc.) and DUR performed. Watch for "list" of patients where the compounded preparation is delivered to the practitioner and no patient profile kept and no DUR performed.*		
5.00	Does the pharmacy distribute sterile compounded preparations to practitioners for office use?		
6.00	Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?		
7.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing? *If so, does the pharmacy have central fill contracts with these pharmacies for patient specific preparations or do they provide non-patient specific compounded preparations to other pharmacies?*		
8.00	If the pharmacy compounds sterile preparations for animals, does the compounding meet the same standards as compounding for human patients?		
9.00	Does the pharmacy compound allergen extracts?		
10.00	Does the pharmacy compound radiopharmaceuticals?		
11.00	Does the pharmacy compound parenteral preparations?		
12.00	Does the pharmacy compound ophthalmic preparations?		
13.00	Does the pharmacy compound inhalation preparations?		
14.00	Does the pharmacy compound parenteral suspensions?		
15.00	Does the pharmacy compound preservative-free parenterals?		

16.00	Does the pharmacy make a copy of an approved product? *Indicate under what circumstances and how it is documented. For example, product is in short supply as verified on FDA Web site.* Indicate volume or percent compounded currently in note.		
17.00	Are products to be compounded appropriately identified as **low-risk**? 1. Not more than three sterile drug packages used 2. Sterile equipment 3. Compounded in an ISO Class 5 hood in an ISO Class 7 clean room (if ISO Class 5 hood NOT in ISO Class 7 clean room, max BUD 12 hours) 4. Limited basic closed system aseptic transfers and manipulations		
18.00	Are products to be compounded appropriately identified as **medium-risk**? 1. Uses four or more sterile ingredients 2. Complex aseptic manipulations other than single volume transfer 3. Compounded sterile preparation (CSP) is to be administered to multiple patients or to one patient on multiple occasions 4. Compounding process of unusually long duration (dissolution, homogeneous mixing)		
19.00	Are products to be compounded appropriately identified as **high-risk**? 1. Made with nonsterile ingredients, nonsterile devices, or nonsterile containers 2. Prepared with sterile ingredients but exposed to <ISO Class 5 air 3. Greater than a six-hour delay before sterilization 4. Purity of components assumed but not verified		
20.00	Are **immediate use** compounds appropriately identified? 1. Aseptically compounded 2. Simple transfer ≤ 3 commercially manufactured non-hazardous products 3. Not > 2 entries into any container 4. Admin begins ≤ 1 hour from start of compounding		
21.00	Are products to be compounded appropriately identified as **hazardous**? *National Institute for Occupational Safety and Health (NIOSH) list of drugs. Hazardous drugs exhibit: carcinogenicity, teratogenicity, or other developmental toxicity, reproductive toxicity, organ toxicity at low dose, or genotoxicity.*		
22.00	For animal compounding, is the pharmacist knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used?		
23.00	For animal compounding, is it determined and documented if the animal is used for food (meat, milk, eggs, etc.)? *Or that the animal is a pet?*		

24.00	For animal compounding, is the pharmacist familiar with drug residues in the food chain and withdrawal times? *How?*						
25.00	For animal compounding, is the pharmacist familiar with regulations regarding drug use in performance animals? *How?*						
		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**	
	Inspector Notes:						

	Component Selection and Use *If any part of a question is no, enter "N" and explain the observation.*	**Y/N/?/NA**	**Note**
26.00	**Does the pharmacy make any compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?**		
27.00	Are certificates of analysis (COAs) obtained for all APIs? *Are COAs domestic or foreign in origin? Select several products from the shelf and ask to see the COAs for those products.*		
28.00	Does the pharmacy perform any testing/analysis of APIs? *If so, indicate how API is selected for testing, what tests are performed and if tested in-house or sent to an outside lab - indicate which lab in notes.*		
29.00	If the source is a foreign FDA facility, does the pharmacy obtain information on the last FDA inspection of that facility and a copy of the report?		
30.00	Are USP- or NF-grade substances used, if available?		
31.00	If compendial quality components are not available, are chemically pure, analytical reagent grade or American Chemical Society-certified components used? *How is it determined the products are free from impurities that raise human or animal safety concerns?*		
32.00	Are other means used to establish purity and safety? *Describe the means, such as* lot analysis, *manufacturer reputation, reliability of source.*		
33.00	Examine the labeling on the APIs. Do any of the labels state "For Research Purposes Only" or "Not for Drug Use" or "Veterinary Use only" or similar? Or have non-standard labels (such as handwritten or from another pharmacy)? *If so, view invoices and record the source of these items and photos. Indicate how vet use only products are segregated to prevent them from being used for preparations compounded for humans.*		
34.00	Do all substances and components have a complete label including a batch control or lot number, an expiration date, and are marked with the date of receipt?		

35.00	For substances without an expiration date assigned by the manufacturer or supplier, does the pharmacy have a procedure to assign a conservative expiration date and is it followed? *Containers labeled with date of receipt and the expiration date assigned is not greater than three (3) years, is supported with data and/or testing, and takes into consideration the nature of the component, its degradation mechanism, the container in which it's packaged, and the storage conditions.*		
36.00	Are all APIs labeled with the date they were received?		
37.00	Does the pharmacy repackage APIs into smaller containers for ease of use? *If so, how is the expiration date determined for the repackaged product?*		
38.00	Are bulk component containers labeled with appropriate OSHA hazard communication labels and are hazardous substances segregated?		
39.00	When manufactured products are used for compounding, do the labels contain a lot number and expiration date?		
40.00	When manufactured products are used for compounding, are all the other excipients in the product considered relative to the use, effectiveness, and stability of the compounded preparation to be made?		
41.00	Are any preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons? *How does the pharmacy determine this?*		
42.00	If compounding for food producing animals, does the compounder have a list of components prohibited for use?		
43.00	If components are used that are derived from ruminant animals (cow, sheep, goat) does the pharmacy obtain documentation that the component is in compliance with federal laws governing processing, use, and importation? *That the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist.*		
44.00	**Does the pharmacy compound its own stock solutions or components that are then used to compound a finished product? *If so, how are BUDs determined?***		
45.00	• Are the compounded stock solutions prepared in batches that are exposed longer than 12 hours at 2-8°C (25-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before being sterilized?		
46.00	• Are all compounded stock solutions that will be used as a component of a finished product tested for sterility and stability? *Explain the process.*		

47.00	• When using its own compounded stock solution, is it used without dilution in a final preparation (repackaged as-is into smaller or unit-of-use packages)? *If so, are these preparations given extended BUDs? How is the BUD determined?*		
48.00	• When using its own compounded stock solution, is it used as a component of a preparation (made less concentrated by the addition of a diluent or other component)? *If so, are these preparations given extended BUDs? How is the BUD determined?*		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	Environment ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
49.00	If the facility performs both sterile and nonsterile compounding, are the areas separated and distinct?		
50.00	Is entry into the sterile compounding areas limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?		
51.00	Does the ante-room have a line of demarcation or other separation of the dirty to the clean side?		
52.00	Are carts used to bring supplies from the storeroom kept on the outside of the line of demarcation?		
53.00	Are carts used in the clean room/buffer room kept on the clean side of the line of demarcation?		
54.00	Are all surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating?		
55.00	Are walls painted with white epoxy based paint or other impermeable surface, and are they seamless or have sealed seams where panels meet and corners with no cracks?		
56.00	Are the ceiling tiles composed of a vinyl surface, with the tiles caulked and sealed and are the seams where the walls meet the ceiling caulked and sealed? *If no, describe what is present.*		

57.00	Is the floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall? *If no, describe what is present.*		
58.00	Does the clean room or ante-room have dust collecting overhangs, such as ceiling utility pipes, or ledges? *Are all sprinkler heads flush with the ceiling?*		
59.00	Are the exposed surfaces of the light fixtures smooth, mounted flush, and sealed?		
60.00	Is there a sink with hot and cold running water located in the ante room or near the sterile compounding area that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands, and is there an eyewash station?		
61.00	Is there a sink or a floor drain in the clean room/buffer room? (This is not allowed)		
62.00	Are all air ducts controlling air flow into the sterile compounding area equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment?		
63.00	Are incoming air ducts through HEPA filters on or near the ceiling and are air return ducts low on the walls to facilitate turbulent air flow in the ante-room and clean room?		
64.00	Is there any particle generating equipment (computers, refrigerators, etc.) in the clean room/buffer room or anteroom? *If so, indicate equipment and room.*		
65.00	If there is particle generating equipment in the clean room or ante-room, is the equipment located by an air return so air flows over and out of the room taking particles with it, and has this air flow has been confirmed by smoke testing? *View certification report for the room and specifically look at particle counts taken in the area of the equipment.*		
66.00	Does the sterile compounding area have a fan? *Has it been validated to not affect airflow in the ISO Class 5 PEC?*		
67.00	Are coffee, water, chewing gum, candy, or food items prohibited from the clean room/buffer area or ante-room?		
68.00	Are sterile compounded products prepared with aseptic manipulations entirely within ISO Class 5 or better air quality hood or shielded laminar flow work area using only sterile ingredients, products, components, and devices?		

69.00	If no (for example compounding with non-sterile APIs), does the pharmacy have appropriate equipment to sterilize the finished product? *List isterilizing equipment used in notes (filters, autoclave, etc.).*		
70.00	Is the ISO Class 5 compounding area located within an ISO Class 7 clean room or buffer area? *For laminar airflow workbenches, CAI, or CACI that are NOT located in an ISO Class 7 buffer room fill out the questions at the end of this section.*		
71.00	Does the ISO Class 7 clean room or buffer area door lead into an ISO Class 7 or 8 ante room? *Indicate if the ante room is ISO Class 7 or 8.*		
72.00	Is the ISO 7 clean room positive pressure to the ISO 7 or 8 ante room? *Record pressure differential.*		
73.00	Is the hazardous compounding room and hazardous drug storage area negative pressure to the ISO 7 ante room? *Record pressure differential.*		
74.00	Is the ISO Class 7 or 8 ante room positive pressure to the general pharmacy areas? *Record the pressure differential.*		
75.00	Are pressure differential monitoring procedures in place including an alarm or alert when there is an excursion? *Verify by viewing daily logs and ensure a plan is in place if discrepancy is found.*		
76.00	If the clean room and anteroom are not fully enclosed, is the air flow measured across the openings? *Record the air flow.*		
77.00	Are air flow monitoring procedures in place including an alarm or alert if the air flow drops below the limit? *Verify by viewing daily logs and ensure a plan is in place if discrepancy is found.*		
78.00	Is the temperature of the compounding area controlled by a thermostat and an adequate air conditioning system (anteroom and cleanroom) maintained between 64-72°F (18-22°C)? *View records and record temperature of the clean room at the time of inspection.*		
79.00	Is the humidity monitored daily and in the range of 35%-60% in the sterile compounding area? *View records and record humidity at the time of inspection.* Relative Humidity levels between 35% and 60% are recommended (below 35% allows static levels above recommended values. Above 60% promotes microbial growth).		
80.00	Are the blowers on ISO 5 laminar airflow workbenches (LAFW) or barrier isolators operated continuously during compounding activity, including during interruptions of less than eight hours?		

81.00	When the LAFW blower is turned off and before other personnel enter to perform compounding activities, is only one garbed person allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces?		
82.00	Are the doors into the ante-room from the general pharmacy area and from the anteroom into the clean room interlocked to prevent both being open at the same time?		
83.00	Are the inside and outside doors of a pass-through interlocked to prevent both being open at the same time?		
	LAFW NOT located in ISO Class 7 buffer area:		
84.00	Is compounding restricted to low-risk preparations with a maximum BUD of 12 hours?		
85.00	Are all garbing requirements adhered to?		
86.00	Is the LAFW located in an area that is maintained under sanitary conditions only be traveled by persons engaging in the compounding of sterile preparations?		
87.00	Does the location contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, or are adjacent to construction sites, warehouses, or food preparation areas?		
88.00	Is the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent)?		
	CAI or CACI NOT located in ISO Class 7 buffer area:		
89.00	Does the CAI/CACI maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP? *NOTE: for certification, particle counts must be sampled 6 to 12 inches upstream of the critical exposure site.*		
90.00	Does the pharmacy have documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments?		
91.00	Is the CAI or CACI located in an area that is maintained under sanitary conditions and only be traveled by persons engaging in the compounding of sterile preparations?		
92.00	For <u>hazardous</u> compounding in a CACI that is NOT located in a buffer area, is the CACI located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH?		

		Substantially Compliant		Somewhat Compliant		Substantially Non-Compliant
	Inspector Notes:					

	Cleaning and Disinfection *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
93.00	Are all personnel that perform cleaning activities in the compounding areas appropriately trained (including housekeeping or other outside personnel if used for cleaning)?		
94.00	Are all personnel performing cleaning appropriately garbed?		
95.00	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*		
96.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area and are buckets inverted to prevent moisture accumulation?		
97.00	Are tools appropriately labeled to prevent them from being used inappropriately? For example, a mop used for the floors cannot also be used for the ceilings and walls.		
98.00	Are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies documented?		
99.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Note if any cleaning agents are expired.*		
100.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores? *Indicate how often a sporicidal agent is used. List products used in note.*		
101.00	Are sanitizing agents rotated or alternated to reduce the risk of producing resistant strains of organisms? *How often?*		
102.00	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?		
103.00	Does the cleaning of the ISO 5 PEC include cleaning with sterile water **and** sanitizing with sterile 70% IPA using a nonlinting wipe?		

104.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?		
105.00	Does daily cleaning include the floors starting from the clean room and working outwards? *Floor cleaning is not to occur during compounding.*		
106.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?		
107.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement? *Note frequency of change.*		
108.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.)* Check inside bins and shelving for dust if you are garbed.		
109.00	Is enough time allocated for cleaning activities?		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**

	Inspector Notes:

	Training and Garbing ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
110.00	Is there documentation that all compounding personnel have passed an initial and subsequent annual written exams for quality assurance procedures for the appropriate risk level and including hazardous drugs?		
111.00	Is there documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling hazardous drugs?		
112.00	Are pharmacists and technicians performing compounding using hazardous drugs appropriately trained in the safe handling, garbing, cleaning, and disinfection procedures and waste disposal of hazardous drugs and materials?		
113.00	Does training include operation of any equipment that may be used when preparing compounded sterile products? *Documentation needs to include training on operation, troubleshooting, and annual competency evaluation.*		

114.00	Does the pharmacy use relief personnel from outside agencies to perform sterile compounding? How are training and certifications verified? *View documentation.*		
115.00	Are personnel prohibited from entering the clean room or ante room if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection? *Include observations in the comments.*		
116.00	Are personnel required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas? *Include observations in the comments.*		
117.00	Are personnel required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc.? *Include observations in the comments.*		
118.00	Are personnel prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed? *Include observations in the comments.*		
119.00	Is garbing performed from the dirtiest to the cleanest starting with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe)?		
120.00	Does garbing then progress to head and facial hair covers and masks? *Eye shields are optional unless using cleaning agents or preparing hazardous drugs.*		
121.00	Is hand cleaning performed in the ante-room and does it include removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds? Are hands and arms then dried with a non-linting disposable towel or a hand dryer? *Scrub brushes are NOT recommended as they cause skin irritation and damage.*		
122.00	Is the gown nonshedding (and preferably disposable) with sleeves that fit snugly around the wrists (some prefer to cut a small hole for the thumb to keep the sleeves from riding up) and enclosed at the neck?		
123.00	Is all bare skin covered on the arms and the legs (no bare ankles, wrists, etc.)?		
124.00	Prior to donning sterile gloves, is a waterless alcohol based surgical hand scrub with persistent activity used and are hands allowed to dry? *Note: Purell is NOT appropriate. Must have residual activity.*		

125.00	Upon leaving the sterile product compounding area, are gowns taken off and disposed of?		
126.00	If gowns are not disposed of, are they left in the ante-room and not reused for longer than one shift?		
127.00	Do pharmacists or other personnel enter the ante-room and cross the line of demarcation without donning shoe covers or dedicated shoes? *Do personnel traverse back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes?*		
128.00	Do pharmacists or other personnel enter the clean room without fully washing and garbing (wearing just a mask to check technician's work, for example)?		
129.00	Is there documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations.*		
130.00	Is there documentation that compounding personnel have passed an annual (every six months for those performing high risk compounding) observed gowning procedure and gloved fingertip sampling test? *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU/plate upon revalidation.*		
131.00	Is there documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that compound low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.*		
132.00	Is there documentation that a media fill test procedure is performed for each compounding employee at least semi-annually for individuals that compound high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.*		

133.00	Do the media-fill testing procedures include media selection, fill volume, incubation time and temperature, inspection of filled units, documentation, interpretation of results, and action levels with the corrective actions required?							
		Substantially Compliant		**Somewhat Compliant**			**Substantially Non-Compliant**	
	Inspector Notes:							

	Environmental Monitoring ***If any part of a question is no, answer the whole question "no" and explain the observation.***	**Y/N/?/NA**	**Note**
134.00	Sterile Compounding: Have all cleanrooms, laminar airflow workbenches, BSCs, CAIs, CACIs, and barrier isolators been certified?		
135.00	Does the pharmacy have an ISO Class 5 shielded laminar workflow area built in to the room (not a hood) and is it certified?		
136.00	Is certification performed at least every six months and whenever a device or room is moved or major work is done to the space?		
137.00	Are certification reports available? *Note the date of the last certification.* *Obtain copies the certification reports and use them to answer the following questions. Note any findings that are "fail" and any findings outside of guidelines that require action yet are indicated as "pass". Indicate what action was taken as a result.*		
138.00	Is the PIC familiar with what testing is required and interpretation of results, have action levels have been identified, and are these further customized based on trended data of performance?		
139.00	Is certification performed by a qualified certifier? (USP states "qualified individual" with no detail). Note the name of certifier, company, and contact information, and if the certifier is CETA National Board of Testing (CNBT) accredited.		
140.00	Is certification to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is it noted on the report? *If not, indicate the standards used as indicated on the report. (Environmental monitoring to CETA CAG-009-00 Viable Environmental Sampling and Gowning Evaluation may also be listed)*		

141.00	Has the equipment used by the certifier been calibrated to the manufacturer's recommended intervals at a minimum, and is that equipment identified in the report by model, SN, last calibration date (or date when next calibration is due)? *The certification report will typically include the calibration certificates for the equipment used.*		
142.00	Does each test on the certification report have a clear indication of pass or fail?		
143.00	**Are the HEPA filtered air changes per hour (ACPH) measured for the compounding rooms?**		
144.00	• Is the ISO Class 7 non-hazardous sterile compounding room certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources? *No more than half the total ACPH are allowed from air recirculated through PECs.*		
145.00	• Is the ISO class 7 ante-room certified as having a minimum of 30 ACPH?		
146.00	• Is the ISO class 8 ante-room certified as having a minimum of 20 ACPH? *No criteria set - a minimum of 20 ACPH is commonly referred to by the FDA and others.*		
147.00	• Is the ISO class 7 hazardous sterile compounding room certified as having a minimum of 30 ACPH? *Typically all of the air will be from outside.*		
148.00	• If a CACI is used, is the room in which it is located certified to maintain a minimum of 12 ACPH?		
149.00	**Was air pattern analysis using smoke testing performed?** ***And is the smoke flow described in the report for the various tests such as turbulent, sluggish, smooth, etc.?***		
150.00	• Was air pattern analysis conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions?		
151.00	• Was air pattern analysis conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs?		
152.00	• Was air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow?		

153.00	**Was differential pressure or displacement airflow measured? *Will be one or the other for each room.***		
154.00	• Was the differential pressure measured to be at least 0.02 water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed?		
155.00	• Was the displacement airflow (for low and medium-risk non-hazardous rooms only) measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the ante-room. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*		
156.00	**Were particle counts measured? *Include particles of 0.5mm and larger.***		
157.00	• Were all particle counts taken during dynamic conditions? *Verify by asking personnel present at the time of certification.*		
158.00	• Are ISO Class 5 areas and hoods certified as having less than 3,520 particles per cubic meter of air?		
159.00	• Are ISO Class 7 areas certified as having less than 352,000 particles per cubic meter of air?		
160.00	• Are ISO Class 8 areas certified as having less than 3,520,000 particles per cubic meter of air?		
161.00	**Was HEPA filter testing performed?**		
162.00	• Were all room HEPA filters leak tested?		
163.00	• If leaks were identified were they fixed?		
164.00	• Were all hood HEPA filters leak tested and air flow velocity measured?		
165.00	• If leaks were identified were they fixed?		
166.00	**Were viable air and surface sampling tests conducted?**		
167.00	• Is appropriate growth media used that supports both bacterial and fungal growth? *List media used in note.*		
168.00	• Was viable air sampling by active impaction using a volumetric air sampling device? *NOTE: Passive air sampling is not compliant with USP Chapter <797>.*		
169.00	• Was each air sample taken in the ISO Class 5 areas or hoods at least 1000 liters in volume *(not 500 liters for a bacterial plate and 500 liters for fungal/mold plate)? Note: recommendation is 1000 liters. Minimum is 400 liters.*		
170.00	• Was each air sample taken in the ISO Class 7 or 8 areas at least 400 liters in volume?		

171.00	• Was viable surface sampling performed on all direct compounding areas (inside of ISO 5 rooms or hoods), in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc., performed?		
172.00	• Did any of the viable samples exceed the USP recommended microbial action levels (or internal action levels if more restrictive)? Classification / Air Sample / Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate ISO Class 7 >10 CFU/m3 >5 CFU/plate ISO Class 8 >100 CFU/m3 >100 CFU/plate *Note: CFUs are TOTAL of bacterial plus fungal/mold plates.* *Note: If less than 1000 liters (= one cubic meter) is used for the air sample, the number of CFUs found must be multiplied by the appropriate factor to equal one cubic meter of air.*		
173.00	• Were all CFUs detected analyzed to determine the organism down to the genus? *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*		
174.00	• Were any mold, yeast, coagulase positive staphylococcus, or gram negative rods detected? *If yes, immediate remediation and investigation into the cause must be conducted.*		
175.00	• Did the testing report indicate that it included growth promotion testing and sterility quality control testing of the media plates? *Positive and negative control tests important to validate results of viable testing.*		
176.00	• Did the testing results report include media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer?		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	Compounding equipment ***If any part of a question is no, enter "N" and explain the observation.***	Y/N/?/NA	Note
177.00	Sterile Compounding: Appropriate equipment available and in good working order including appropriate equipment for handling hazardous materials. *View maintenance and calibration logs.*		
178.00	Are scales, balances, and other equipment used for measuring or weighing calibrated at least annually? *Indicate by whom.*		

179.00	Are any Automated Compounding Devices (ACDs) used? *Such as those used to compound parenteral nutrition and repeater pumps.*		
180.00	Are there written policies for the use, daily calibration and maintenance g of the ACD?		
181.00	Is there documentation of the ACD tubing being changed every 24 hours?		
182.00	Is the ACD used when performing media fill testing?		
183.00	Does the pharmacy have a lyophilizer? *If so, note the volume or percent of products per week produced using the lyophilizer and if the lyophilizer is part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures.*		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	Compounding Procedures ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
184.00	Are all procedures performed in a manner designed to minimize the risk of touch contamination and are gloves and critical sites sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a nonlinting wipe?		
185.00	Are objects that shed particles prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?		
186.00	Are essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) wiped down with sterile 70% IPA before bring brought into the buffer or clean area?		
187.00	Are supplies required for the scheduled operations of the shift prepared and decontaminated by wiping or spraying the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area (preferably) on one or more movable carts?		
188.00	Are compounding employees using appropriate aseptic technique? Observe from outside. *May require inspector to garb and enter clean room. Inspector to record observations after exit from the clean room (may not bring in objects, pens, paper, etc.). Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA), etc.*		

189.00	Are supplies required for back-up or general support of operations stored on the designated shelving in the buffer or clean area? *Look for excessive accumulation as all products will have to be re-cleaned upon monthly cleaning.*		
190.00	Do compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use?		
191.00	Are all rubber stoppers of vials and bottles and the neck of ampules sanitized every time with sterile 70% IPA (and a wait of at least 10 seconds to dry) prior to the introduction of a needle or spike for the removal of product?		
192.00	After the preparation of every admixture, are the contents of the container-thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other issues?		
193.00	Are opened or needle punctured single-dose containers (bags, bottles, syringes, or vials) that are opened or punctured in worse than ISO Class 5 air used within one (1) hour and the remaining contents discarded? *How are they marked?*		
194.00	Are single-dose vials exposed to ISO Class 5 or cleaner air used within six (6) hours of the initial puncture and any remaining contents discarded? *How are they marked?*		
195.00	Are the remaining contents of opened single-dose ampules discarded immediately? *May not be stored for any time period.*		
196.00	Are multiple-dose vials that are formulated for removal of portions on multiple occasions (usually containing preservatives) assigned a BUD of 28 days or the manufacturer's specific BUD (whichever is less) after the initial entry or puncture?		
197.00	Before being dispensed (and/or administered), are the clarity of solutions visually confirmed, the identity and amounts of ingredients, the procedures to prepare and sterilize CSPs, and the specific release criteria are reviewed to assure their accuracy and completeness?		

197.90	Is the compounding record complete? *1. Official or assigned name, strength and dosage of the preparation* *2. Names, lot numbers and expiration dates of all components* *3. Total quantity or number of units compounded* *4. Person compounding the preparation* *5. Person performing the quality control procedures* *6. Person who approved the preparation* *7. Date of compounding* *8. Assigned internal identification number or prescription number* *9. Assigned BUD and reference if extended beyond USP guidelines* *10. Duplicate label* *11. Sterilization method (if applicable)* *12. Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if appropriate.*		
198.00	Are procedure for in-process checks followed? *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product and documentation of the compounding accuracy is by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*		
199.00	Do labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials?		
200.00	Do labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include identifiers for the persons preparing and performing the final verification, stability or BUD, flow rate (if applicable), and appropriate packaging and labeling of hazardous materials?		
201.00	Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**		
202.00	Sterile Compounding: Are BUDs greater than 24 hours documented with justification based on USP guidelines, testing or literature. *Verify documentation.*		

203.00	Are BUDs assigned that are longer than the USP Chapter 797 guidelines? **Low Risk** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk** 24 hours room temp, 3 days refrigerated, 45 days frozen		
204.00	Is there a process for determining and assigning a BUD that addresses single-dose containers, multiple-dose containers, and proprietary bag ad vial systems? *Multiple dose containers 28 days after initial opening or entry, six hours for single dose containers kept in ISO Class 5 air, and one hour for worse than ISO Class 5 air, 0 for opened ampules (not allowed) or other if by documentation from manufacturer.*		
205.00	Are appropriate sterilization methods used and documented? *Ensure P&Ps in place that address determining the appropriate type of sterilization method, equipment to be used, documentation to be kept and testing to be performed.*		
206.00	Does the pharmacy use non-sterile empty vials and vial stoppers or closures and terminally sterilize them with on on-site autoclave?		
207.00	**Filter sterilization:** Is there documentation that: 1. The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP 2. That filtering is completed rapidly without filter replacement 3. That confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration? *View documentation on batch records of items sterilized by filtration to confirm.*		
208.00	**Steam sterilization:** Is there documentation that: 1. The autoclave has been validated for the exposure time and mass of the items to be sterilized 2. Ensures live steam contacts all ingredients and surfaces to be sterilized 3. Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization 4. Heated filtered air is evenly distributed throughout the chamber with a blower 5. That the CSP will not be adversely affected by the steam and heat 6. The description of steam sterilization includes conditions and duration for specific CSPs		

209.00	**Dry heat sterilization:** Is there documentation that: 1. Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture 2. Sufficient space is left between materials to allow for air circulation 3. The description of dry heat sterilization includes conditions and duration for specific CSPs 4. That the effectiveness of steam sterilization is verified each time using appropriate biological indicators 5. The oven is equipped with a system for controlling temperature and exposure period?		
210.00	**Depyrogenation by dry heat:** Is there documentation that: 1. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes 2. The description of the cycle and duration for specific load items 3. The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs) 4. Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins		

		Substantially Compliant		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	Finished Preparation Release Checks and Tests ***If any part of a question is no, answer the whole question "no" and explain the observation.***	**Y/N/?/NA**	**Note**
211.00	Sterile Compounding: Is there a process in place to sample prepared products for potency and/or contamination and recall actions to take if discrepancies are found? For suspensions, is the particle size measured?		
212.00	Are products checked for particulates or other foreign matter against both a light and a dark colored background?		
213.00	Are there checks for container and closure integrity?		
214.00	Is compounding accuracy documented by verification of steps?		
215.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*		

216.00	Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*		
217.00	Sterility testing: Is sterility testing performed for each batch of CSPs that have extended BUDS, are prepared in batches of more than 25 identical containers, or are exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized?		
218.00	Are the appropriate quantities of units for each batch tested? For parenterals, if the number if the number of units in the batch: 1. Less than 100, test 10% or four units, whichever is greater 2. 100 up to 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Less than 200 containers, test 5% or 2 containers, whichever is greater 2. 200 or more containers, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above. *View records to confirm appropriate number tested. View records of products failing tests including investigation and action taken.*		
219.00	If items are dispensed or distributed prior to sterility testing completion, is there a written procedure requiring daily observation of the incubated media and requirement of an immediate recall if there is any evidence of microbial growth? *In addition, is the patient and the physician of the patient to whom a potentially contaminated CSP was administered notified of the potential risk?*		
220.00	Are all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials), or in multiple dose vials for administration to multiple patients, or exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized tested to ensure that they do not contain excessive bacterial endotoxins? *View results of testing and indicate number or percentage of units tested.*		
221.00	Are products tested for purity and potency? *How are the products selected for testing?*		

222.00	View testing records. Have products that failed sterility, endotoxin, purity or potency testing been dispensed or distributed and not recalled? *How are 'inconclusive' results handled?*						
223.00	Does the pharmacy have its own lab to perform testing? If so, what testing is performed in house?						
224.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*						
		Substantially Compliant		**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes:						

The information and comments obtained in the supplement sections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

Florida Board of Pharmacy
Compounding Rules Committee
2014-2015 Annual Regulatory Plan

Rule Number	Rule Title	Rulemaking Action	Reason for Rulemaking	Additional Details on Reason for Rulemaking	Description of Current Rule or Statute to be Implemented	Description of Changes to be Made in Rulemaking	Economic Impact	Highly Technical or Complicated
64B16-New Rule /TBD	Non-Resident Pharmacies/ Sterile Compounding	New Rule	Other (Provide a detailed explanation)	To implement pending legislation regarding out-of-state sterile compounders shipping into Florida	The statutes to be implemented: 465.0156; 465.0158, F.S.; HB 7077	The rule will be implementing changes to the Practice Act which involve non-resident sterile compounding	None	No
64B16-New Rule /TBD	Outsourcing Facilities	New Rule	Other (Provide a detailed explanation)	The Committee will review the status of Outsourcing Facilities to determine the need for obtaining a Sterile Compounding Permit.	The statutes to be implemented: 465.0196; 465.022; F.S.; HB3204	Address the status of those Outsourcing facilities located in the geographical boundaries of Florida	None	No
64B16-27.700	Definition of Compounding	Rule Amendment	Update Rule (Explain, e.g. correct pattern of injury resulting from lack of standards; board priority; not updated since 1908)	To clarify the definition of compounding and too review or amend in relation to subsection (3) based on recent legislation: HB 3204; HB 7077	The statute to be implemented is 465.0196; 465.022, F.S.	Update definition and updates based on committee recommendations	None	No
64B16-27.700	Standards for Sterile Compounding	Rule Amendment	Update Rule (Explain, e.g. correct pattern of injury resulting from lack of standards; board priority; not updated since 1908)	To amend or standards as needed and to incorporate USP chapter on compounding	The current rules establishes the standards for sterile compounding	Update and Amend	None	No

By the Committee on Health Policy

588-01081-14 2014662__

A bill to be entitled

An act relating to nonresident pharmacies; amending s. 465.0156, F.S.; conforming provisions to changes made by the act; deleting a requirement that the Board of Pharmacy refer regulatory issues affecting a nonresident pharmacy to the state where the pharmacy is located; creating s. 465.0158, F.S.; requiring registered nonresident pharmacies to obtain a permit in order to ship, mail, deliver, or dispense compounded sterile products into this state; requiring submission of an application and a nonrefundable fee; specifying requirements; requiring the Department of Health to inform permittees of any law or rule changes; authorizing the board to deny, revoke, or suspend a permit for certain actions; providing dates by which certain registered and unregistered nonresident pharmacies must obtain a permit; authorizing the Board of Pharmacy to adopt rules; providing for future repeal; amending s. 465.017, F.S.; authorizing the department to inspect registered nonresident pharmacies; requiring nonresident pharmacies to pay for the costs of such inspections; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (4) and (5) of section 465.0156, Florida Statutes, are amended to read:

465.0156 Registration of nonresident pharmacies.—

(4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, s. 465.0158, or ~~with~~ any requirement of this section in accordance with ~~the provisions of~~ this chapter.

(5) In addition to the prohibitions of subsection (4), the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with ~~the provisions of~~ this chapter for conduct that ~~which~~ causes or could cause serious bodily injury or serious psychological injury to a human or animal in ~~resident of~~ this state ~~if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral~~.

Section 2. Section 465.0158, Florida Statutes, is created to read:

465.0158 Nonresident pharmacy compounded sterile products permit.—A nonresident pharmacy registered under s. 465.0156 must also hold a compounded sterile products permit issued under this section in order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.

(1) Application for a permit shall be submitted on a form furnished by the board, together with a nonrefundable permit fee as provided under s. 465.022(14). The board may require such information as it deems reasonably necessary to carry out the purposes of this section, including information pertaining to registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services.

(2) As a condition of initial permitting and permit

renewal, the owners, officers, and prescription department manager or pharmacist in charge of the nonresident pharmacy must attest in writing that they have read and understand the laws and rules governing sterile compounding in this state and that any compounded sterile product shipped, mailed, delivered, or dispensed into this state will meet or exceed this state's standards for sterile compounding.

(a) The department shall notify all compounded sterile products permittees when state laws or rules affecting the standards for sterile compounding in this state are adopted or revised, along with the effective date of the law or rule.

(b) If the department fails to notify a permittee of a change in state laws or rules, or the permittee does not receive notification of applicable rules, the permittee remains legally obligated to meet or exceed this state's standards with respect to any compounded sterile product shipped, mailed, delivered, or dispensed into this state. The board may provide an exception to this requirement by rule if the sterile compounding laws and rules of the state in which the nonresident pharmacy is located directly conflict with a board rule for sterile compounding in this state but provide a comparable standard of product safety and integrity.

(3) A nonresident pharmacy may not ship, mail, deliver, or dispense any compounded sterile product into this state which:

(a) Was compounded in violation of the laws and rules of the state in which the nonresident pharmacy is located; or

(b) Does not meet or exceed this state's sterile compounding standards as provided in subsection (2).

(4) To the extent feasible, biennial permit renewal shall

be timed to coincide with nonresident pharmacies' registration renewal under s. 465.0156.

(5) In accordance with this chapter, the board may deny, revoke, or suspend the permit of, or fine or reprimand, a nonresident pharmacy for:

(a) Failure to comply with the requirements of this section; or

(b) Conduct that causes or could cause serious bodily injury or serious psychological injury to a human or animal in this state.

(6) A registered nonresident pharmacy that is currently shipping, mailing, delivering, or dispensing compounded sterile products into this state may continue to do so if such products meet or exceed the standards for sterile compounding in this state and the pharmacy is issued a nonresident pharmacy compounded sterile products permit on or before January 31, 2015.

(7) A nonresident pharmacy seeking registration in this state under s. 465.0156 on or after July 1, 2014, may not ship, mail, deliver, or dispense a compounded sterile product into this state until it has received the sterile compounded products permit required under this section.

(8) The board shall adopt rules necessary to administer this section.

(9) This section is repealed October 1, 2018, unless reenacted by the Legislature.

Section 3. Section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.—

(1) Duly authorized agents and employees of the department may ~~shall have the power to~~ inspect in a lawful manner at all reasonable hours any pharmacy, including a nonresident pharmacy registered under s. 465.0156, and any~~,~~ hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a) Determining if any provision ~~of the provisions~~ of this chapter or any rule adopted ~~promulgated~~ under its authority is being violated;

(b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c) Securing such other evidence as may be needed for prosecution under this chapter.

(2) The cost for inspecting a nonresident pharmacy shall be reimbursed by the pharmacy. The cost to the pharmacy is limited to the actual costs incurred by the department.

(3)~~(2)(a)~~ Except as permitted by this chapter~~,~~ and chapters 406, 409, 456, 499, and 893 or upon the written authorization of the patient, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs may ~~shall not~~ be furnished only ~~to any person other than~~ to the patient for whom the drugs were dispensed, or her or his legal representative, ~~or~~ to the department pursuant to existing law, or if~~, in the event that~~ the patient is incapacitated or unable to request such ~~said~~ records, her or his spouse ~~except upon the written authorization of such patient~~.

(a) Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

(b) The board shall adopt rules establishing ~~to establish~~ practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules must ~~shall~~ be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

Section 4. This act shall take effect July 1, 2014.

A bill to be entitled

An act relating to sterile compounding; amending s. 465.003, F.S.; defining the terms "compounding" and "outsourcing facility" as used in the Florida Pharmacy Act; amending s. 465.0156, F.S.; providing additional grounds for administrative discipline of a nonresident pharmacy, to which penalties apply; authorizing the Board of Pharmacy to administratively discipline a nonresident pharmacy for certain conduct; deleting a requirement that the board first refer such conduct to a certain regulatory or licensing agency; providing that a nonresident pharmacy is subject to certain health care fraud provisions; creating s. 465.0158, F.S.; requiring a nonresident pharmacy and an outsourcing facility to hold a nonresident sterile compounding permit to ship, mail, deliver, or dispense a compounded sterile product into this state; providing permit application requirements; requiring the Department of Health to conduct an onsite inspection of a nonresident pharmacy or contract with a third party to conduct such inspection; requiring the department to accept a satisfactory inspection report from specified entities; providing restrictions on the shipment, mailing, delivery, or dispensation of a compounded sterile product by permittees, nonresident pharmacies, and applicants for

registration as a nonresident pharmacy; authorizing the board to administratively discipline a permittee for failing to comply with or violating certain provisions; providing rulemaking authority; amending s. 465.017, F.S.; authorizing the department to inspect a registered nonresident pharmacy or permittee; requiring such pharmacy or permittee to bear the cost of the inspection; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (18) and (19) are added to section 465.003, Florida Statutes, to read:

465.003 Definitions.—As used in this chapter, the term:

(18) "Compounding" means a practice in which a licensed pharmacist or, in the case of an outsourcing facility, a person acting under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug or product to create another drug or product.

(19) "Outsourcing facility" means a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, Pub. L. No. 113-54, at which sterile compounding of a product is conducted.

Section 2. Subsections (4) and (5) of section 465.0156, Florida Statutes, are amended, and subsection (6) is added to

that section, to read:

465.0156 Registration of nonresident pharmacies.—

(4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, s. 465.017(2), s. 465.0158, or ~~with~~ any requirement of this section in accordance with the provisions of this chapter.

(5) In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with ~~the provisions of~~ this chapter for conduct which causes or could cause serious bodily ~~injury~~ or ~~serious~~ psychological injury to a human or serious bodily injury to a nonhuman animal in ~~resident of~~ this state ~~if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral~~.

(6) A nonresident pharmacy is subject to the provisions of s. 456.0635.

Section 3. Section 465.0158, Florida Statutes, is created to read:

465.0158 Nonresident sterile compounding permit.—

(1) In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state, a nonresident pharmacy registered under s. 465.0156, or an outsourcing facility as defined in s. 465.003, must hold a

nonresident sterile compounding permit. For purposes of this section, an outsourcing facility is a nonresident facility that is not a pharmacy.

(2) An application for a nonresident sterile compounding permit shall be submitted on a form furnished by the board. The board may require such information as it deems reasonably necessary to carry out the purposes of this section. The fee for an initial permit and biennial renewal of the permit shall be set by the board pursuant to s. 465.022(14).

(3) An applicant must submit to the board to obtain an initial permit, or to the department to renew a permit, the following:

(a) Proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services if the applicant is eligible for such registration pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.

(b) Proof of registration as a nonresident pharmacy, pursuant to s. 465.0156, unless the applicant is an outsourcing facility, in which case the application must include proof of the active and unencumbered license, permit, or registration issued by the state, territory, or district in which the outsourcing facility is physically located which allows the outsourcing facility to engage in compounding and ship, mail, deliver, or dispense a compounded sterile product into this state.

(c) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager or pharmacist in charge, that:

1. The applicant has read and understands the laws and rules governing sterile compounding in this state.

2. A compounded sterile product shipped, mailed, delivered, or dispensed into this state will meet or exceed this state's standards for sterile compounding.

3. A compounded sterile product shipped, mailed, delivered, or dispensed into this state must not have been, and may not be, compounded in violation of the laws and rules of the state in which the applicant is located.

(d) The applicant's existing policies and procedures for sterile compounding, which must comply with pharmacy standards in United States Pharmacopoeia chapter 797, to the extent required by board rule, or current good manufacturing practices for an outsourcing facility.

(e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report must reflect compliance with the requirements of this chapter. An inspection report is current if the inspection was conducted no more than 6 months before the date of submission of the application for the initial permit or no more than 1 year before the date of submission of the application for renewal of the permit. If an applicant is unable

to submit a current inspection report due to unforeseeable or other acceptable circumstances, as established by rule, or if an inspection has not been performed, the department shall:

1. Conduct, or contract with an entity approved by the board to conduct, an onsite inspection, for which all costs shall be borne by the applicant;

2. Accept a satisfactory inspection report in lieu of an onsite inspection, as determined by rule, from an entity approved by the board; or

3. Accept an inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54, in lieu of an onsite inspection.

(4) A permittee may not ship, mail, deliver, or dispense a compounded sterile product into this state if the product was compounded in violation of the laws or rules of the state in which the permittee is located or does not meet or exceed this state's sterile compounding standards.

(5) In accordance with this chapter, the board may deny, revoke, or suspend the permit of, fine, or reprimand a permittee for:

(a) Failure to comply with the requirements of this section;

(b) A violation listed under s. 456.0635, s. 456.065, or s. 456.072;

(c) A violation under s. 465.0156(5); or

(d) A violation listed under s. 465.016.

(6) A nonresident pharmacy registered under s. 465.0156 which ships, mails, delivers, or dispenses a compounded sterile product into this state may continue to do so if the product meets or exceeds the standards for sterile compounding in this state, the product is not compounded in violation of any law or rule of the state where the pharmacy is located, and the pharmacy applies for and is issued a permit under this section on or before February 28, 2015.

(7) An applicant registering on or after October 1, 2014, as a nonresident pharmacy under s. 465.0156 may not ship, mail, deliver, or dispense a compounded sterile product into this state until the applicant is registered as a nonresident pharmacy and is issued a permit under this section.

(8) The board shall adopt rules as necessary to administer this section, including rules for:

(a) Developing an application for the permit required by this section.

(b) Determining how, when, and under what circumstances an inspection of a nonresident sterile compounding permittee shall be conducted.

(c) Evaluating and approving entities from which a satisfactory inspection report will be accepted in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory agency of the state, territory, or district where the applicant is located.

Section 4. Section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.—

(1) Duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are compounded, manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a) Determining if any ~~of the~~ provision~~s~~ of this chapter or any rule adopted ~~promulgated~~ under its authority is being violated;

(b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c) Securing such other evidence as may be needed for prosecution under this chapter.

(2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156 or a nonresident sterile compounding permittee under s. 465.0158 pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.

(3) ~~(2)~~ (a) Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a

pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs shall not be furnished to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, in the event that the patient is incapacitated or unable to request said records, her or his spouse except upon the written authorization of such patient. Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

(b) The board shall adopt rules establishing ~~to establish~~ practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules shall be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

Section 5. This act shall take effect October 1, 2014.

Effective: January 1, 2011

West's Florida Statutes Annotated Currentness
Title XXXII. Regulation of Professions and Occupations (Chapters 454-493) (Refs & Annos)
Chapter 465. Pharmacy (Refs & Annos)
465.014. Pharmacy technician

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

(2) Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed $50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed $50; is at least 17 years of age; and has completed a pharmacy technician training program approved by the Board of Pharmacy. Notwithstanding any requirements in this subsection, any registered pharmacy technician registered pursuant to this section before January 1, 2011, who has worked as a pharmacy technician for a minimum of 1,500 hours under the supervision of a licensed pharmacist or received certification as a pharmacy technician by certification program accredited by the National Commission for Certifying Agencies is exempt from the requirement to complete an initial training program for purposes of registration as required by this subsection.

(3) A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to register as a pharmacy technician.

(4) Notwithstanding the requirements of this section or any other provision of law, a pharmacy technician student who is enrolled in a pharmacy technician training program that is approved by the board may be placed in a pharmacy for the purpose of obtaining practical training. A pharmacy technician student shall wear identification that indicates his or her student status when performing the functions of a pharmacy technician, and registration under this section is not required.

(5) Notwithstanding the requirements of this section or any other provision of law, a person who is licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without paying a registration fee or filing an application with the board to register as a pharmacy technician.

(6) As a condition of registration renewal, a registered pharmacy technician shall complete 20 hours biennially of continuing education courses approved by the board or the Accreditation Council for Pharmacy Education, of which 4 hours must be via live presentation and 2 hours must be related to the prevention of medication errors and pharmacy law.

(7) The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department. The board may adopt other rules as necessary to administer this section.

(8) If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. 456.072(1) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. 456.072(1) or a violation of this chapter which occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. 456.072(2) against the applicant or registrant.

CREDIT(S)

Laws 1979, c. 79-226, § 1; Laws 1986, c. 86-256, § 10. Amended by Laws 1997, c. 97-103, § 242, eff. July 1, 1997; Laws 1997, c. 97-264, § 192, eff. July 1, 1997; Laws 1999, c. 99-397, § 120, eff. July 1, 1999; Laws 2008, c. 2008-216, § 2, eff. June 23, 2008; Laws 2008, c. 2008-216, § 3, eff. Jan. 1, 2010; Laws 2008, c. 2008-216, § 4, eff. Jan. 1, 2011.

LIBRARY REFERENCES

Health 129, 178, 198.
Westlaw Topic No. 198H.

RESEARCH REFERENCES

Encyclopedias

Pharmacy Technicians, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 75.

West's F. S. A. § 465.014, FL ST § 465.014

Current through Ch. 272 (End) of the 2013 1st Reg. Sess. of the 23rd Legislature

END OF DOCUMENT

Effective: July 1, 2012

West's Florida Statutes Annotated Currentness
Title XXXII. Regulation of Professions and Occupations (Chapters 454-493) (Refs & Annos)
Chapter 465. Pharmacy (Refs & Annos)
465.003. Definitions

As used in this chapter, the term:

(1) “Administration” means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.

(2) “Board” means the Board of Pharmacy.

(3) “Consultant pharmacist” means a pharmacist licensed by the department and certified as a consultant pharmacist pursuant to s. 465.0125.

(4) “Data communication device” means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.

(5) “Department” means the Department of Health.

(6) “Dispense” means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

(7) “Institutional formulary system” means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy.

(8) “Medicinal drugs” or “drugs” means those substances or preparations commonly known as “prescription” or “legend” drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.

(9) “Patent or proprietary preparation” means a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act.

(10) “Pharmacist” means any person licensed pursuant to this chapter to practice the profession of pharmacy.

(11)(a) “Pharmacy” includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1. The term “community pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term “institutional pharmacy” includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as “health care institutions,” where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term “nuclear pharmacy” includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term “special pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term “Internet pharmacy” includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

(b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term “not present and on duty” shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(12) “Pharmacy intern” means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.

(13) “Practice of the profession of pharmacy” includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of this subsection, “other pharmaceutical services” means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. “Practice of the profession of pharmacy” also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189.

(14) “Prescription” includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term “prescription” also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

(15) “Nuclear pharmacist” means a pharmacist licensed by the department and certified as a nuclear pharmacist pursuant to s. 465.0126.

(16) “Centralized prescription filling” means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17) “Automated pharmacy system” means a mechanical system that delivers prescription drugs received from a

Florida licensed pharmacy and maintains related transaction information.

CREDIT(S)

Laws 1979, c. 79-226, § 1; Laws 1981, c. 81-259, § 322; Laws 1981, c. 81-302, § 14; Laws 1982, c. 82-179, § 1; Laws 1983, c. 83-101, § 1; Laws 1983, c. 83-216, § 36; Laws 1983, c. 83-329, § 29; Laws 1985, c. 85-35, § 1; Laws 1986, c. 86-256, § 2; Laws 1988, c. 88-172, § 1; Laws 1989, c. 89-77, § 1. Amended by Laws 1994, c. 94-218, § 123, eff. May 20, 1994; Laws 1997, c. 97-103, § 239, eff. July 1, 1997; Laws 1997, c. 97-264, § 87, eff. July 1, 1997; Laws 1999, c. 99-397, § 118, eff. July 1, 1999; Laws 2002, c. 2002-182, § 1, eff. July 1, 2002; Laws 2004, c. 2004-25, § 1, eff. May 11, 2004; Laws 2004, c. 2004-387, § 1, eff. July 1, 2004; Laws 2007, c. 2007-152, § 2, eff. July 1, 2007; Laws 2012, c. 2012-60, § 2, eff. July 1, 2012.

HISTORICAL AND STATUTORY NOTES

Prior Provisions for Legislative Review of Regulatory Statutes:

Laws 1982, c. 82-179, § 2, provided that provisions of that law amending Florida Statutes Chapter 465 were to be repealed on October 1, 1986, and to be reviewed by the legislature pursuant to s. 11.61, the Regulatory Sunset Act. Laws 1983, c. 83-265, § 3, repealed Laws 1982, c. 82-179, § 2.

CROSS REFERENCES

Complimentary drugs, distribution, see § 499.028.
Medicinal drugs, making, altering and forging prescriptions, see F.S.A. § 831.30.
Prescription drugs,
Pedigree papers, see § 499.01212.
Storage and handling, recordkeeping, see § 499.0121.

LIBRARY REFERENCES

Health 198.
Westlaw Topic No. 198H.

RESEARCH REFERENCES

ALR Library

79 ALR 5th 409, Civil Liability of Pharmacists or Druggists for Failure to Warn of Potential Drug Interactions in Use of Prescription Drug.

44 ALR 5th 393, Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User.

Encyclopedias

Physician's Failure to Protect Third Party from Harm by Nonpsychiatric Patient, 43 Am. Jur. Proof of Facts 2d 657.

Injuries from Drugs, 7 Am. Jur. Proof of Facts 3d 1.

Failure to Warn as Proximate Cause of Injury, 8 Am. Jur. Proof of Facts 3d 547.

Proof of Physical Disability of Driver of Motor Vehicle, 53 Am. Jur. Proof of Facts 3d 67.

Medical Necessity Defense, Fla. Jur. 2d Criminal Law Substantive Principles and Offenses § 1371.

Drug; Dispense; Distribute, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 63.

Pharmacy, Pharmacist, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 66.

Prescription, Proprietary Drug, Administration, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 67.

Pharmacy Technicians, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 75.

Centralized Prescription Filling, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 89.

Prescription Drugs; Pedigree Papers, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 105.

Forms

Florida Pleading and Practice Forms § 34:104, Complaint--Failure to Meet Minimum Requirements for Safe Practice Under the Florida Pharmacy Act.

NOTES OF DECISIONS

1. Construction and application

Drugs not properly “dispensed” are, per se, “misbranded” for purposes of offense of adulterating or misbranding prescription drugs. Rodriguez v. State, App. 3 Dist., 67 So.3d 326 (2011). Health 982

No private cause of action was created by amendment of Pharmacy Act's definition of “dispense”--as element of dispensing, pharmacist shall, prior to actual physical transfer, interpret and assess prescription order for potential adverse reactions, interactions, and dosage regimen he deems appropriate, shall certify that medicinal drug called for by prescription is ready for transfer, and shall provide counseling on proper drug usage, either orally or in writing, if deemed necessary. Johnson v. Walgreen Co., App. 1 Dist., 675 So.2d 1036 (1996). Action 3; Health 198; Products Liability 225; Products Liability 303

Definitions enacted under § 465.031 (repealed, see, now this section) in 1961 had no bearing on question of whether acts allegedly committed prior to effective date of such definitions constituted violations of law relating to pharmacists. Hall v. Florida Bd. of Pharmacy, 177 So.2d 833 (1965). Health 106

2. Practice of pharmacy

Hydrocodone shipped to consumers from defendants' Internet pharmacy without being reviewed by a pharmacist was not properly “dispensed,” thus supporting convictions for adulterating or misbranding prescription drugs. Rodriguez v. State, App. 3 Dist., 67 So.3d 326 (2011). Health 982

Pharmacy is a “profession” in the general sense of the word. Lee v. Gaddy, 133 Fla. 749, 183 So. 4 (1938). Health 110

Practice of pharmacy was the art of practice of preparing and preserving drugs and of compounding and dispensing medicines according to prescriptions of physicians; the occupation of apothecary or pharmaceutical chemist. Ex parte Sarros, 116 Fla. 86, 156 So. 396 (1934).

3. Criminal prosecutions

Prescription defense is available to an innocent possessor of a controlled substance who has a legally recognized reason for the possession of controlled substance prescribed to another individual. McCoy v. State, App. 1 Dist., 56 So.3d 37 (2010). Controlled Substances 51

In prosecution for sale of prescription drug without prescription in which State's drug chemist was unable to say whether substance sold by defendant was prescription drug, and trial court improperly took judicial notice that such substance required prescription, State failed to prove substance which defendant sold was within definition of “medicinal drugs” or “drugs.” Block v. State, App. 2 Dist., 437 So.2d 792 (1983). Health 989

To convict defendant for violating § 465.015 proscribing sale of prescription drug without prescription, State had to prove drug which defendant sold was among those defined by statute as “medicinal drugs” or “drugs.”

Block v. State, App. 2 Dist., 437 So.2d 792 (1983). Health 982

4. Civil actions

Pharmacists who are licensed under Florida Pharmacy Act are not “health care providers” who are entitled to presuit notice under statutes governing medical malpractice actions. GalenCare, Inc. v. Mosley, App. 2 Dist., 59 So.3d 138 (2011), rehearing denied. Health 807

Complaint that alleged that pharmacies filled numerous lawful prescriptions for customer for narcotic medications too closely in time, within days of having filled previous prescriptions, and that customer subsequently died as result of combined drug overdose, stated cause of action for negligence; strong public policy supported imposition of duty on pharmacies to warn customers of risks inherent in filling repeated and unreasonable prescriptions with potentially fatal consequences. Powers v. Thobhani, App. 4 Dist., 903 So.2d 275 (2005), review granted 924 So.2d 812, review denied 934 So.2d 1182. Products Liability 114; Products Liability 133; Products Liability 225

5. Pharmacies

Requirement of supervision of retail drug establishment by licensed pharmacist could not be extended so as to cover all operations of drugstore including those which were unrelated by their nature to the preparation and sale of controlled drugs and medicines. State v. Leone, 118 So.2d 781 (1960). Health 198

A drug room situated in a hospital operated by a practicing physician is not a “drug store” and regulated by the statutes respecting pharmacists, where the drug room was used for the exclusive accommodations of hospital patients and prescriptions of other physicians were not filled, and orders on the drug room for medicine for patients were in the nature of memoranda rather than prescriptions which were filled either by physicians or some one in their constant presence and direction. Parr v. Spires, 41 So.2d 336 (1949). Health 198

5.5. Prescription

Trial court's failure to instruct jury on a prescription defense to the charge of trafficking in hydrocodone, to which defendant did not object, was fundamental error at trial on the trafficking charge and a charge of possession of cocaine with intent to sell; prescription defense was defendant's primary defense to the trafficking charge, and properly instructed jury could have found that defendant had implied authority from his mother, who had a valid prescription for the pills that were found at defendant's bedside, to safeguard the pills until he could return them to her. Ramirez v. State, App. 4 Dist., 2013 WL 163461 (2013). Controlled Substances 98

The prescription defense to a charge of trafficking in a controlled substance is not limited to the person holding a valid prescription, but may also be asserted by any individual authorized by the prescription holder to hold the medications on his or her behalf; this extension derives from statutes which allow pharmacists to dispense prescription drugs to a patient's agent. Ramirez v. State, App. 4 Dist., 2013 WL 163461 (2013). Controlled Substances 51

6. Voluntary duty

Pharmacy did not undertake voluntary duty by giving warning to pharmacy patron not to drive while using medication and placing a “use caution while driving” label on prescription bottle, and therefore its actions did not broaden the zone of foreseeable risk to unidentified third parties including motorist who was injured in collision with pharmacy patron who fell asleep at the wheel while under the influence of medication, where pharmacy was required to give warnings under state administrative code and state statute. Dent v. Dennis Pharmacy, Inc., App. 3 Dist., 924 So.2d 927 (2006), review dismissed 939 So.2d 1058, rehearing denied. Health 752; Products Liability 133; Products Liability 225

7. Duty, generally

The administratively mandated inherent benefit of additional drug regimen review did not, by itself, create a legal duty to nursing home resident nor did it expand the consultant pharmacist's role beyond that of an administrative advisor, and the Pharmacy Act specifically restricted pharmacist from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, or practicing medicine. Estate of Johnson ex rel. Johnson v. Badger Acquisition Of Tampa LLC, App. 2 Dist., 983 So.2d 1175 (2008), rehearing denied. Health 198; Health 706

8. Pharmacist review

Evidence supported finding that defendants knowingly packaged and delivered misbranded drugs, thus supporting convictions for adulterating or misbranding prescription drugs; defendants were the sons of a pharmacist who had worked alongside their father for years and had working knowledge of the operations of the pharmacy, rendering them well aware that it was not legally permissible to ship hydrocodone to consumers from Internet pharmacy without pharmacist review. Rodriguez v. State, App. 3 Dist., 67 So.3d 326 (2011). Health 989

West's F. S. A. § 465.003, FL ST § 465.003

Current through Ch. 272 (End) of the 2013 1st Reg. Sess. of the 23rd Legislature

END OF DOCUMENT

64B16-27.1001 Practice of Pharmacy.

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:

(a) Supervise and be responsible for the controlled substance inventory.

(b) Receive verbal prescriptions from a practitioner.

(c) Interpret and identify prescription contents.

(d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.

(e) Engage in professional communication with practitioners, nurses or other health professionals.

(f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:

(a) Interpret and identify all incoming orders.

(b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.

(c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.

(d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 11-18-07, Amended 1-1-10.

64B16-27.410 Registered Pharmacy Technician, to Pharmacist Ratio.

(1) Registered pharmacy technicians may assist a pharmacist in performing professional services within a pharmacy environment provided that no pharmacist shall supervise more than one registered pharmacy technician unless otherwise permitted by the Florida Board of Pharmacy. A pharmacist's supervision of a registered pharmacy technician in a working environment requires that a registered pharmacy technician be under the direct personal supervision of a pharmacist.

(2) The prescription department manager or consultant pharmacist of record is required to submit a written request and receive approval prior to the pharmacy's allowing a pharmacist to supervise more than one registered pharmacy technician as permitted by law. Such requests shall be reviewed and pre-approved by Board staff according to the guidelines adopted herein, and submitted to the Board for ratification.

(3) The request to practice with a ratio greater than 1:1 shall include a brief description of the workflow needs that justify the ratio request. The brief description of workflow needs shall include the operating hours of the pharmacy, number of pharmacists, registered interns, and registered pharmacy technicians employed.

(4) A pharmacy that employs pharmacy technicians shall meet the following conditions:

(a) Establish written job descriptions, task protocols, and policies and procedures that pertain to duties performed by the registered pharmacy technician and provide this information to the Board upon request;

(b) Establish that each registered pharmacy technician is knowledgeable in the established job descriptions, task protocols, and policy and procedures in the pharmacy setting in which the technician is to perform his or her duties;

(c) Ensure that the duties assigned to any registered pharmacy technician do not exceed the established job descriptions, task protocols, and policy and procedures, nor involve any of the prohibited tasks in Rule 64B16-27.420, F.A.C.; or

(d) Ensure that each registered pharmacy technician receives employer-based or on-the-job training in order for the registered pharmacy technician to assume his or her responsibilities and maintain documentation of the training.

(5) The pharmacy shall maintain a policy and procedure manual with regard to registered pharmacy technicians which shall include the following:

(a) Supervision by a pharmacist;

(b) Minimum qualifications as established by law;

(c) Documentation of in-service education and/or on-going training and demonstration of competency, specific to practice site and job function;

(d) General duties and responsibilities of registered pharmacy technicians;

(e) Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

(f) All functions related to prescription processing;

(g) All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;

(h) rescription refill and renewal authorization;

(i) Registered pharmacy technician functions related to automated pharmacy systems; and

(j) Continuous quality improvement program.

Rulemaking Authority 465.005 FS. Law Implemented 465.014, 893.07(1)(b) FS. History–New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10.

64B16-27.420 Registered Pharmacy Technician Responsibilities.

(1) Registered pharmacy technicians may assist the pharmacist in performing the following tasks:

(a) Retrieval of prescription files, patient files and profiles and other such records pertaining to the practice of pharmacy;

(b) Data Entry;

(c) Label preparation;

(d) The counting, weighing, measuring, pouring and mixing of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system;

(e) Initiate communication to a prescribing practitioner or their medical staffs (or agents) regarding patient prescription refill authorization requests. For the purposes of this section "prescription refill" means the dispensing of medications pursuant to a prescriber's authorization provided on the original prescription;

(f) Initiate communication to confirm the patient's name, medication, strength, quantity, directions and date of last refill;

(g) Initiate communication to a prescribing practitioner or their medical staff (or agents) to obtain clarification on missing or illegible dates, prescriber name, brand/generic preference, quantity, DEA registration number or license numbers; and

(h) May accept authorization for a prescription renewal. For the purposes of this section, "prescription renewal" means the dispensing of medications pursuant to a practitioner's authorization to fill an existing prescription that has no refill remaining.

(2) Registered Pharmacy technicians shall not:

(a) Receive new verbal prescriptions or any change in the medication, strength or directions;

(b) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(c) Conduct a final verification of dosage and directions;

(d) Engage in prospective drug review;

(e) Provide patient counseling;

(f) Monitor prescription usage; and

(g) Override clinical alerts without first notifying the pharmacist.

(3) Nuclear pharmacy permits allow the registered pharmacy technician to receive diagnostic orders only. The pharmacist must receive therapy or blood product procedure orders.

(4)(a) All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as a "registered pharmacy technician"; and

(b) All registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History–New 8-31-87, Formerly 21S-4.0025, Amended 7-30-91, Formerly 21S-27.420, 61F10-27.420, 59X-27.420, Amended 2-23-98, 1-1-10, 8-26-12.